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Part II

MEDICARE-MEDICAID ANTIFRAUD AND ABUSE AMENDMENTS

REPORT

BY THE

COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE

[To accompany H.R. 3]

together with

SEPARATE AND ADDITIONAL VIEWS

[And Including Cost Estimate of the Congressional Budget Office]

JULY 12, 1977.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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95TH CONGRESS } HOUSE OF REPRESENTATIVES { REPT. 95-393
1st Session } { PART 2

MEDICARE-MEDICAID ANTI-FRAUD AND ABUSE AMENDMENTS

JULY 12, 1977.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. STAGGERS, from the Committee on Interstate and Foreign Commerce, submitted the following

REPORT

together with

SEPARATE AND ADDITIONAL VIEWS

[Including cost estimate of the Congressional Budget Office]

[To accompany H.R. 3 which on Jan. 4, 1977, was referred jointly to the Committee on Ways and Means and the Committee on Interstate and Foreign Commerce]

The Committee on Interstate and Foreign Commerce, to whom was referred the bill (H.R. 3) to strengthen the capability of the Government to detect, prosecute, and punish fraudulent activities under the medicare and medicaid programs, and for other purposes, having considered the same, report favorably thereon with four amendments and recommend that the bill as amended do pass.

The amendments are as follows:

1. On page 1, strike out line 5 and all that follows through line 7 on page 27 and insert in lieu thereof the following:

PROHIBITION AGAINST ASSIGNMENT BY PHYSICIANS AND OTHERS OF CLAIMS FOR SERVICES; CLAIMS PAYMENT PROCEDURES FOR MEDICAID PROGRAM

SEC. 2. (a)(1) Section 1842(b)(5) of the Social Security Act is amended by adding at the end thereof the following new sentence: "No payment which under the preceding sentence may be made directly to the physician or other person providing the service involved (pursuant to an assignment described in subparagraph (B)(ii) of paragraph (3)) shall be made to anyone else under a reassignment or power of attorney (except to an employer or facility as described in clause (A) or (B) of such sentence); but nothing in this sub-

section shall be construed (i) to prevent the making of such a payment in accordance with an assignment from the individual to whom the service was provided or a reassignment from the physician or other person providing such service if such assignment or reassignment is made to a governmental agency or entity or is established by or pursuant to the order of a court of competent jurisdiction, or (ii) to preclude an agent of the physician or other person providing the service from receiving any such payment if (but only if) such agent does so pursuant to an agency agreement under which the compensation to be paid to the agent for his services for or in connection with the billing or collection of payments due such physician or other person under this title is unrelated (directly or indirectly) to the amount of such payments or the billings therefor, and is not dependent upon the actual collection of any such payment.".

(2) Section 1815 of such Act is amended by adding at the end thereof the following new subsection:

"(c) No payment which may be made to a provider of services under this title for any service furnished to an individual shall be made to any other person under an assignment or power of attorney; but nothing in this subsection shall be construed (1) to prevent the making of such a payment in accordance with an assignment from the provider if such assignment is made to a governmental agency or entity or is established by or pursuant to the order of a court of competent jurisdiction, or (2) to preclude an agent of the provider of services from receiving any such payment if (but only if) such agent does so pursuant to an agency agreement under which the compensation to be paid to the agent for his services for or in connection with the billing or collection of payments due such provider under this title is unrelated (directly or indirectly) to the amount of such payments or the billings therefor, and is not dependent upon the actual collection of any such payment.".

(3) Section 1902(a)(32) of such Act is amended to read as follows:

"(32) provide that no payment under the plan for any care or service provided to an individual shall be made to anyone other than such individual or the person or institution providing such care or service, under an assignment or power of attorney or otherwise; except that—

"(A) in the case of any care or service provided by a physician, dentist, or other individual practitioner, such payment may be made (i) to the employer of such physician, dentist, or other practitioner if such physician, dentist, or practitioner is required as a condition of his employment to turn over his fee for such care or service to his employer, or (ii) (where the care or service was provided in a hospital, clinic, or other facility) to the facility in which

the care or service was provided if there is a contract arrangement between such physician, dentist, or practitioner and such facility under which such facility submits the bill for such care or service; and

"(B) nothing in this paragraph shall be construed (i) to prevent the making of such a payment in accordance with an assignment from the person or institution providing the care or service involved if such assignment is made to a governmental agency or entity or is established by or pursuant to the order of a court of competent jurisdiction, or (ii) to preclude an agent of such person or institution from receiving any such payment if (but only if) such agent does so pursuant to an agency agreement under which the compensation to be paid to the agent for his services for or in connection with the billing or collection of payments due such person or institution under the plan is unrelated (directly or indirectly) to the amount of such payments or the billings therefor, and is not dependent upon the actual collection of any such payment;".

(4) The amendments made by this subsection shall apply with respect to care and services furnished on or after the date of the enactment of this Act.

(b)(1) Section 1902(a) of the Social Security Act is amended—

(A) by striking out "and" at the end of paragraph (35);

(B) by striking out the period at the end of paragraph (36) and inserting in lieu thereof "; and";

(C) by inserting immediately after paragraph (36) the following new paragraph:

"(37) provide for claims payment procedures which (A) ensure that 90 percentum of claims for payment made for services covered under the plan and furnished by health care practitioners through individual or group practices or through shared health facilities are paid within 30 days of the date of receipt of such claims and that 99 per centum of such claims are paid within 60 days of the date of receipt of such claims, and (B) provide for procedures of prepayment and postpayment claims review, including review of appropriate data with respect to the recipient and provider of a service and the nature of the service for which payment is claimed, to ensure the proper and efficient payment of claims and management of the program." ; and

(D) by inserting at the end thereof the following paragraph:

"The requirement of clause (A) of paragraph (37) with respect to a State plan may be waived by the Secretary if he finds that the State has exercised good faith in trying to meet such requirement.".

(2) Section 1903 of such Act is amended—

(A) by redesignating paragraph (6) of subsection (a) as paragraph (7);

(B) by inserting after paragraph (5) of subsection (a) the following new paragraph:

"(6) subject to subsection (l), an amount equal to 90 per centum of so much of the sums expended during such quarter as are attributable to the arranging and providing of such programs of educational and technical assistance (provided through such means, including outreach offices, the media, and telephone hotlines, as the Secretary determines to be appropriate) to health care practitioners who furnish, through individual or group practices or through shared health facilities, services covered under the plan, as the Secretary determines are likely to expedite the filing and payment of claims for payment for such services provided by such practitioners; plus" ; and

(C) by inserting after subsection (k) the following new subsection:

"(l)(1) Payment shall not be made under subsection (a)(6) for a quarter ending after September 30, 1980.

"(2) If the aggregate of the amounts of payments to be made in accordance with subsection (a)(6) for any calendar quarter to States exceeds $1,250,000, the amount of the payment to be made under such subsection for the quarter to each such State shall be an amount which bears the same ratio to the amount determined for the quarter under the subsection to the State as $1,250,000 bears to the amount required to make payments for the quarter in accordance with such subsection to all of the States.".

(3)(A) The amendments made by paragraph (1) shall apply to calendar quarters beginning on and after January 1, 1978, with respect to State plans approved under title XIX of the Social Security Act.

(B) The amendments made by paragraph (2) shall apply, with respect to expenditures made, under a State plan approved under title XIX of the Social Security Act, in calendar quarters beginning on and after January 1, 1978.

DISCLOSURE OF OWNERSHIP AND RELATED INFORMATION

SEC. 3. (a)(1) Part A of title XI of the Social Security Act is amended by inserting immediately after section 1123 the following new section:

"DISCLOSURE OF OWNERSHIP AND RELATED INFORMATION

"SEC. 1124. (a)(1) The Secretary shall by regulation or by contract provision provide that each disclosing entity (as defined in paragraph (2)) shall—

"(A) as a condition of the disclosing entity's participation in, or certification or recertification under, any

of the programs established by titles V, XVIII, and XIX, or

"(B) as a condition for the approval or renewal of a contract or agreement between the disclosing entity and the Secretary or the appropriate State agency under any of the programs established under titles V, XVIII, and XIX,

supply the Secretary or the appropriate State agency with full and complete information as to the identity of each person with an ownership or control interest (as defined in paragraph (3)) in the entity.

"(2) As used in this section, the term 'disclosing entity' means an entity which is—

"(A) a provider of services (as defined in section 1861(u), other than a fund), an independent clinical laboratory, or a renal disease facility;

"(B) an entity (other than an individual practitioner or group of practitioners) that furnishes, or arranges for the furnishing of, items or services with respect to which payment may be claimed by the entity under any plan or program established pursuant to title V or under a State plan approved under title XIX; or

"(C) a carrier or the other agency or organization that is acting as a fiscal intermediary or agent with respect to one or more providers of services (for purposes of part A or part B of title XVIII, or both, or for purposes of a State plan approved under title XIX) pursuant to (i) an agreement under section 1816, (ii) a contract under section 1842, or (iii) an agreement with a single State agency administering or supervising the administration of a State plan approved under title XIX.

"(3) As used in this section, the term 'person with an ownership or control interest' means, with respect to an entity, a person who—

"(A)(i) has directly or indirectly (as determined by the Secretary in regulations) an ownership interest of 5 per centum or more in the entity; or

"(ii) is the owner (in whole or in part) of an interest of 5 per centum or more in any mortgage, deed of trust, note, or other obligation secured (in whole or in part) by the entity or any of the property or assets thereof; or

"(B) is an officer or director of the entity, if the entity is organized as a corporation; or

"(C) is a partner in the entity, if the entity is organized as a partnership.

"(b) To the extent determined to be feasible under regulations of the Secretary, a disclosing entity shall also include in the information supplied under subsection (a)(1), with respect to each person with an ownership or control interest in the entity, the name of any other disclosing entity with respect to which the person is a person with an ownership or control interest.

"(c) A provider of services (as defined in section 1861(u), other than a fund) shall also include in the information supplied under subsection (a)(1) full and complete information as to the identity of each person with an ownership or control interest in any subcontractor (as defined by the Secretary in regulations) in which the provider directly or indirectly has a 5 per centum or more ownership interest.".

(2) Section 1861(j)(11) of such Act is amended to read as follows:

"(11) complies with the requirements of section 1124;".

(b) Clause (C) of section 1866(b)(2) of such Act is amended by inserting "(i)" after "failed", and by adding after "to verify such information," the following: "or (ii) to supply (within such period as may be specified by the Secretary in regulations) upon request specifically addressed to such provider by the Secretary (I) full and complete information as to the ownership of a subcontractor (as defined by the Secretary in regulations) with whom such provider has had, during the previous twelve months, business transactions in an aggregate amount in excess of $25,000, and (II) full and complete information as to any significant business transactions (as defined by the Secretary in regulations), occurring during the five-year period ending on the date of such request, between such provider and any wholly owned supplier or between such provider and any subcontractor,".

(c)(1) Section 1902(a) of such Act (as amended by section 2(b)(1) of this Act) is amended—

(A) by amending paragraph (35) to read as follows:

"(35) provide that any intermediate care facility receiving payments under such plan complies with the requirements of section 1124;";

(B) by striking out "and" at the end of paragraph (36);

(C) by striking out the period at the end of paragraph (37) and inserting in lieu thereof "; and"; and

(D) by inserting after paragraph (37) the following new paragraph:

"(38) require that an entity (other than an individual practitioner or a group of practitioners) that furnishes, or arranges for the furnishings of, items or services under the plan, shall supply (within such period as may be specified in regulations by the Secretary or by the single State agency which administers or supervises the administration of the plan) upon request specifically addressed to such entity by the Secretary or such State agency, respectively, (A) full and complete information as to the ownership of a subcontractor (as defined by the Secretary in regulations) with whom such entity has had, during the previous twelve months, business transactions in an aggregate amount in excess of $25,000, and (B) full and complete information as to any significant business transactions (as defined by the Secretary in regulations), occurring during the five-year period ending on the date

of such request, between such entity and any wholly owned supplier or between such entity and any subcontractor.".

(2) Section 1903(i)(2) of such Act is amended by inserting before the semicolon at the end thereof the following: ", or by reason of noncompliance with a request made by the Secretary under clause (C)(ii) of such section 1866(b)(2) or under section 1902(a)(38)".

(d) The amendment made by subsection (a)(1) shall apply with respect to certifications and recertifications made (and participation in the programs established by title V, XVIII, and XIX of the Social Security Act pursuant to certifications and recertifications made), and fiscal intermediary or agent agreements or contracts entered into or renewed, on and after the date of the enactment of this Act. The remaining amendments made by this section shall take effect on the date of the enactment of this Act; except that the amendments made by paragraphs (1) and (2) of subsection (c) shall become effective October 1, 1977.

PENALTIES FOR DEFRAUDING MEDICARE AND MEDICAID PROGRAMS

SEC. 4. (a) Section 1877 of the Social Security Act is amended to read as follows:

"PENALTIES

"SEC. 1877. (a) Whoever—

"(1) knowingly and willfully makes or causes to be made any false statement or representation of a material fact in any application for any benefit or payment under this title,

"(2) at any time knowingly and willfully makes or causes to be made any false statement or representation of a material fact for use in determining rights to any such benefit or payment,

"(3) having knowledge of the occurrence of any event affecting (A) his initial or continued right to any such benefit or payment, or (B) the initial or continued right to any such benefit or payment of any other individual in whose behalf he has applied for or is receiving such benefit or payment. conceals or fails to disclose such event with an intent fraudulently to secure such benefit or payment either in a greater amount or quantity than is due or when no such benefit or payment is authorized, or

"(4) having made application to receive any such benefit or payment for the use and benefit of another and having received it. knowingly and willfully converts such benefit or payment or any part thereof to a use other than for the use and benefit of such other person,

shall (i) in the case of such a statement, representation, concealment, failure, or conversion by any person in connec-

tion with the furnishing (by that person) of items or services for which payment is or may be made under this title, be guilty of a felony and upon conviction thereof fined not more than $25,000 or imprisoned for not more than five years or both, or (ii) in the case of such a statement, representation, concealment, failure, or conversion by any other person, be guilty of a misdemeanor and upon conviction thereof fined not more than $10,000 or imprisoned for not more than one year or both.

"(b)(1) Whoever solicits or receives any remuneration (including kickbacks, bribes, or rebates, but excluding any amount paid by an employer to an employee for employment in the provision of covered items or services) directly or indirectly, overtly or covertly, in cash or in kind—

"(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of items or services for which payment may be made in whole or in part under this title, or

"(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing or ordering goods, facilities, services, or any item for which payment may be made in whole or in part under this title,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

"(2) Whoever offers or pays any remuneration (including kickbacks, bribes, or rebates, but excluding any amount paid by an employer to an employee for employment in the provision of covered items or services) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—

"(A) to refer an individual to a person for the furnishing or arranging for the furnishing of items or services for which payment may be made in whole or in part under this title, or

"(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering goods, facilities, services, or any item for which payment may be made in whole or in part under this title,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

"(3) Paragraphs (1) and (2) shall not apply to a discount or other reduction in price obtained by a provider of services or other entity reimbursed under this title on a cost basis, if the reduction in price is properly disclosed and reflected in the costs claimed by the provider or entity as reimbursable under this title.

"(c) Whoever knowingly and willfully makes or causes to be made, or induces or seeks to induce the making of, any false statement or representation of a material fact with respect to the conditions or operation of any institution or

facility in order that such institution or facility may qualify (either upon initial certification or upon recertification) as a hospital, skilled nursing facility, or home health agency (as those terms are defined in section 1861), shall be guilty of a felony and upon conviction thereof shall be fined not more than $25,000 or imprisoned for not more than five years, or both.".

(b) Section 1909 of such Act is amended to read as follows:

"PENALTIES

"SEC. 1909. (a) Whoever—

"(1) knowingly and willfully makes or causes to be made any false statement or representation of a material fact in any application for any benefit or payment under a State plan approved under this title,

"(2) at any time knowingly and willfully makes or causes to be made any false statement or representation of a material fact for use in determining rights to such benefit or payment,

"(3) having knowledge of the occurrence of any event affecting (A) his initial or continued right to any such benefit or payment, or (B) the initial or continued right to any such benefit or payment of any other individual in whose behalf he has applied for or is receiving such benefit or payment, conceals or fails to disclose such event with an intent fraudulently to secure such benefit or payment either in a greater amount or quantity than is due or when no such benefit or payment is authorized, or

"(4) having made application to receive any such benefit or payment for the use and benefit of another and having received it, knowingly and willfully converts such benefit or payment or any part thereof to a use other than for the use and benefit of such other person,

shall (i) in the case of such a statement, representation, concealment, failure, or conversion by any person in connection with the furnishing (by that person) of items or services for which payment is or may be made under this title, be guilty of a felony and upon conviction thereof fined not more than $25,000 or imprisoned for not more than five years or both, or (ii) in the case of such a statement, representation, concealment, failure, or conversion by any other person, be guilty of a misdemeanor and upon conviction thereof fined not more than $10,000 or imprisoned for not more than one year or both. In addition, in any case where an individual who is otherwise eligible for assistance under a State plan approved under this title is convicted of an offense under the preceding provisions of this subsection, the State may at its option (notwithstanding any other provision of this title or of such plan) limit, restrict, or suspend the eligibility of that individual for such period (not exceeding one year) as it deems appropriate; but the imposition of a limitation, restriction,

or suspension with respect to the eligibility of any individual under this sentence shall not affect the eligibility of any other person for assistance under the plan, regardless of the relationship between that individual and such other person.

"(b) (1) Whoever solicits or receives any remuneration (including kickbacks, bribes, or rebates, but excluding any amount paid by an employer to an employee for employment in the provision of covered items or services) directly or indirectly, overtly or covertly, in cash or in in kind—

"(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of items or services for which payment may be made in whole or in part under this title, or

"(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering goods, facilities, services, or any item for which payment may be made in whole or in part under this title,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

"(2) whoever offers or pays any remuneration (including kickbacks, bribes, or rebates, but excluding any amount paid by an employer to an employee for employment in the provision of covered items or services) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—

"(A) to refer an individual to a person for the furnishing or arranging for the furnishing of items or services for which payment may be made in whole or in part under this title, or

"(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering goods, facilities, services, or any item for which payment may be made in whole or in part under this title,

shall be guilty of a felony and, upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

"(3) Paragraphs (1) and (2) shall not apply to a discount or other reduction in price obtained by an entity reimbursed under this title on a cost basis if the reduction in price is properly disclosed and reflected in the costs claimed by the entity as reimbursable under this title.

"(c) Whoever knowingly and willfully makes or causes to be made, or induces or seeks to induce the making of, any false statement or representation of a material fact with respect to the conditions or operation of any institution or facility in order that such institution or facility may qualify (either upon initial certification or upon recertification) as a hospital, skilled nursing facility, intermediate care facility, or home health agency (as those terms are employed in this title) shall be guilty of a felony and upon conviction thereof shall be fined not more than $25,000 or imprisoned for not more than five years, or both.".

(c) Section 204(a) of Public Law 94–505 (42 U.S.C. 3524) (relating to annual reports of the Inspector General of the Department of Health, Education, and Welfare) is amended by adding at the end thereof the following sentence: "Such report shall also include an evaluation of the performance of the Attorney General in the investigation and prosecution of criminal violations relating to fraud in the programs of health insurance and medical assistance provided under titles XVIII and XIX of the Social Security Act, and shall include any recommendations with respect to improving the performance of such activities.".

(d) The amendments made by subsections (a) and (b) shall apply with respect to acts occurring and statements or repsentations made on or after the date of the enactment of this Act.

AMENDMENTS RELATED TO PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS

SEC. 5. (a) Section 1152(e) of the Social Security Act is amended to read as follows:

"(e) Where the Secretary finds a Professional Standards Review Organization (whether designated on a conditional basis or otherwise) to be competent to perform review responsibilities, the review, certification, and similar activities otherwise required pursuant to provisions of this Act (other than this part) shall not be applicable with respect to those providers, suppliers, and practitioners being reviewed by such Professional Standards Review Organization, except to the extent specified by the Secretary. Nothing in the preceding sentence shall be construed as rendering inapplicable any provision of this Act wherein requirements with respect to conditions for eligibility to or payment of benefits (as distinct from reviews and certifications made with respect to determinations of the kind made pursuant to paragraphs (1) and (2) of section 1155(a)) must be satisfied.".

(b)(1) Section 1154(b) of such Act is amended—

(A) by striking out "(which may not exceed 24 months)" in the first sentence and inserting in lieu thereof "(which may not exceed 48 months except as provided in subsection (c))";

(B) by inserting ", in addition to review of health care services provided by or in institutions," after "perform" in the first sentence: and

(C) by striking out "or ordered by physicians" and all that follows through "and organizations" in the second sentence and inserting in lieu thereof "by or in institutions (including ancillary services) and, in addition, review of such other health care services as the Secretary may require".

(2) Section 1154 of such Act is further amended by redesignating subsection (c) as subsection (d), and by inserting after subsection (b) the following new subsection:

"(c) If the Secretary finds that an organization designated under subsection (a) has been unable to perform satisfactorily all of the duties and functions required under this part for reasons beyond the organization's control, he may extend such organization's trial period for an additional period not exceeding twenty-four months.".

(c)(1) Section 1155 of such Act is amended—

(A) by striking out "directly or indirectly involved in" in subsection (a)(6)(A) and inserting in lieu thereof "directly responsible for";

(B) by striking out "any financial" in subsection (a)(6)(B) and inserting in lieu thereof "a significant financial";

(C) by inserting after "to such organization" in subsection (f)(2) the following: ", in a manner similar to that provided for under section 1816(c),"; and

(D) by striking out subsection (g) and inserting in lieu thereof the following new subsection:

"(g)(1) Not later than two years after the date of the enactment of the Medicare-Medicaid Anti-Fraud and Abuse Amendments, the Secretary, through the conduct of demonstration projects or otherwise, shall develop effective ambulatory care review methodologies for use by Professional Standards Review Organizations in performing review responsibility with respect to ambulatory care services.

"(2) Where a Professional Standards Review Organization (whether designated on a conditional basis or otherwise) requests review responsibility with respect to services furnished in shared health facilities, the Secretary must give priority to such request, with the highest priority being assigned to requests from organizations located in areas with substantial numbers of shared health facilities.

"(3) The Secretary shall require any Professional Standards Review Organization which is capable of exercising review responsibility with respect to ambulatory care services to perform review responsibility with respect to such services on and after a date not later than two years after the date the organization has been designated as a Professional Standards Review Organization (other than under section 1154).".

(2) Section 111(a) of such Act is amended by inserting after paragraph (8) the following new paragraph:

"(9) The term 'shared health facility' means any arrangement whereby—

"(A) two or more health care practitioners practice their professions at a common physical location;

"(B) such practitioners share (i) common waiting areas, examining rooms, treatment rooms, or other space, (ii) the services of supporting staff, or (iii) equipment;

"(C) such practitioners have a person (who may himself be a practitioner)—

"(i) who is in charge of, controls, manages, or supervises substantial aspects of the arrangement

or operation for the delivery of health or medical services at such common physical location, other than the direct furnishing of professional health care services by the practitioners to their patients; or

"(ii) who makes available to such practitioners the services of supporting staff who are not employees of such practitioners; and

who is compensated in whole or in part, for the use of such common physical location or support services pertaining thereto, on a basis related to amounts charged or collected for the services rendered or ordered at such location or on any basis clearly unrelated to the value of the services provided by the person; and

"(D) at least one of such practitioners received payments on a fee-for-service basis under titles V, XVIII, and XIX in an amount exceeding $5,000 for any one month during the preceding 12 months, or in an aggregate amount exceeding $40,000 during the preceding 12 months;

except that such term does not include a provider of services (as defined in section 1861(u) of this Act), a health maintenance organization (as defined in section 1301 of the Public Health Service Act), a hospital cooperative shared services organization meeting the requirements of section 501(e) of the Internal Revenue Code of 1954, or any public entity.".

(d)(1) Section 1158 of such Act is amended by adding at the end thereof the following new subsection:

"(c) Where a Professional Standards Review Organization (whether designated on a conditional basis or otherwise) has been found competent by the Secretary to assume review responsibility with respect to specified types of health care services or specified providers or practitioners of such services and is performing such reviews, determinations made pursuant to paragraphs (1) and (2) of section 1155(a) in connection with such reviews shall constitute the conclusive determination on those issues (subject to sections 1159, 1171(a)(1), and 1171(d)(3)) for purposes of payment under this Act, and no reviews with respect to those determinations shall be conducted, for purposes of payment, by agencies and organizations which are parties to agreements entered into by the Secretary pursuant to section 1816, carriers which are parties to contracts entered into by the Secretary pursuant to section 1842, or single State agencies administering or supervising the administration of State plans approved under title XIX.".

(2)(A) Section 1152(b)(2) of such Act is amended by striking out "submitted to him by the association, agency, or organization" and inserting in lieu thereof "which shall be developed and submitted by the association, agency, or organization in accordance with subsection (h)".

(B) Section 1152 of such Act is further amended by adding at the end thereof the following new subsection:

"(h)(1) During the development and preparation by an organization of its formal plan under subsection (b)(2) or of any modification of such plan to include review of services in skilled nursing facilities (as defined in section 1861 (j)) or intermediate care facilities (as defined in section 1905 (c)) or review of ambulatory care services, the organization shall consult with the single State agency responsible for administering or supervising the administration of the State plan approved under title XIX for the State in which the organization is located.

"(2) Such plan and any such modification shall be submitted to the Governor of such State, at the time of its submission to the Secretary, for his comments.

"(3) The Secretary, before making the findings described in subsection (b)(2) or a finding regarding the organization's capability to perform review of such services (as the case may be), shall consider any such comments submitted to him by such Governor before the end of the thirty-day period beginning on the date of submission of the plan or of any such modification (as the case may be).

"(4) If, after considering such comments, the Secretary intends to make findings which are adverse to such comments, the Secretary shall provide the Governor making such comments with the opportunity to submit additional evidence and comments on such intended findings during a period of not less than thirty days ending before the findings become effective.".

(C) Section 1154 of such Act (as amended by subsection (b)(2) of this section) is further amended by adding after subsection (d) the following new subsection:

"(e) In determining whether an organization designated on a conditional basis as the Professional Standards Review Organization for any area is substantially carrying out its duties in a satisfactory manner and should be considered a qualified organization, the Secretary shall follow the procedures specified in section 1152(h) (concerning the Secretary's consideration of comments of the Governor of the State in which the organization is located).".

(D) Part B of title XI of such Act is amended by adding after section 1170 the following new section:

"MEMORANDUMS OF UNDERSTANDING; FEDERAL-STATE RELATIONS GENERALLY

"SEC. 1171. (a)(1) Except as provided in paragraph (2), no determination made by a Professional Standards Review Organization pursuant to paragraphs (1) and (2) of section 1155(a) in connection with reviews shall constitute conclusive determinations under section 1158(c) for purposes of payment under title XIX, unless such organization has entered into a memorandum of understanding, approved by the Secretary, with the single State agency responsible for administering or supervising the administration of the State

plan approved under title XIX for the State in which the organization is located (hereinafter in this section referred to as the 'State agency') for the purpose of delineating the relationship between the organization and the State agency and of providing for the exchange of data or information, administrative procedures, coordination mechanisms, and modification of the memorandum at any time that additional responsibility for review by the organization is authorized by the Secretary.

"(2) The requirement of paragraph (1) may be waived by the Secretary if (A) the State agency indicates to the Secretary that it does not wish to enter into a memorandum of understanding with the organization involved, or (B) the Secretary finds that the State agency has refused to negotiate in good faith or in a timely manner with the organization involved.

"(b)(1) The State agency may request a Professional Standards Review Organization which is entering into such a memorandum of understanding with the agency to include in the memorandum a specification of review goals or methods (additional to any such goals or methods contained in the organization's formal plan) for the performance of the organization's duties and functions under this part.

"(2) If the agency and the organization cannot reach agreement regarding the inclusion of any such requested specification, the Secretary shall review such specification and shall require that the specification be included in the memorandum if the Secretary determines that such specification of goals or methods (A) is consistent with the functions of the organization under this part and with the provisions of title XIX and the State's plan approved under such title, and (B) does not seriously impact on the effectiveness and uniformity of the organization's review of health care services paid for under title XVIII and title XIX of this Act.

"(c) Notwithstanding any other provision of this Act, the State agency may contract with any Professional Standards Review Organization located in the State for the performance of review responsibilities in addition to those performed pursuant to this part (and the cost of performance of such additional responsibilities is reimbursable as an expense of the State agency under section 1903(a)) if—

"(1) the State agency formally requests the performance of such additional responsibilities, and

"(2) the performance of such additional responsibilities is not inconsistent with this part and is provided for in an amendment to the State's plan which is approved by the Secretary under title XIX.

"(d)(1) Each State agency may monitor the performance of review responsibilities by Professional Standards Review Organizations located within the State, in accordance with a State monitoring plan which is developed after review and comment by such organizations and is approved by the Secretary. The costs of activities of the State agency under and in

accordance with such plan are reimbursable as an expense of the State agency under section 1903(a).

"(2) A monitoring plan developed and approved under paragraph (1) may include a specification of performance criteria for judging the effectiveness of the review performance of the Professional Standards Review Organizations. If the State agency and the Professional Standards Review Organizations cannot reach agreement regarding such criteria, the Secretary shall assist the agency and organizations in resolving the matters in dispute.

"(3)(A) Whenever a State agency monitoring the performance of review responsibilities by a Professional Standards Review Organization under a plan developed and approved under paragraph (1) submits to the Secretary reasonable documentation that the review determinations of such organization have caused an unreasonable and detrimental impact either on total State expenditures under title XIX or on the quality of care received by individuals under the State's plan approved under such title, and requests the Secretary to act, the Secretary shall, within thirty days from the date of receipt of the documentation, temporarily suspend such organization's authority in whole or in part under section 1158(c) to make conclusive determinations for purposes of payment under title XIX (and he may suspend such authority for purposes of payment under title XVIII) pending a reevaluation of such organization's performance of the responsibilities involved and any appropriate action the Secretary may take as a result of such reevaluation.

"(B) The Secretary shall notify the State agency submitting such documentation, and the organization involved, in writing, of his determination, any subsequent actions taken, and the basis thereof, and shall notify the appropriate committees of the United States House of Representatives and the Senate of any such documentation submitted and the actions taken.

"(e)(1) The Secretary shall in a timely manner establish procedures and mechanisms to govern his relationships with State agencies under this part (specifically including his relationships with such agencies in connecting with their respective functions under the preceding provisions of this section). Such mechanisms shall include periodic consultation by the Secretary with State agency representatives and representatives of Professional Standards Review Organizations regarding relationships between such agencies and such organizations (including the appropriate exchange of data and information between such agencies and such organizations) and other problems of mutual concern, and such procedures shall permit the State agency to be represented on any project assessments conducted by the Secretary with respect to a Professional Standards Review Organization located within its State.

"(2) Each Professional Standards Review Organization shall provide to the State agency for the State in which it is

located, upon request, data or information which the Secretary requires such organizations to report to him routinely on a periodic basis, and such other data or information as the Secretary authorizes to be disclosed.".

(3)(A) Section 1155(e)(1) of such Act is amended by inserting "(other than a skilled nursing facility, as defined in section 1861(j))" after "the review committees of a hospital or other operating health care facility or organization".

(B) Section 1155(a) of such Act is amended—

(i) by inserting "(except as provided in paragraph (7))" in paragraph (1) after "institutional and non-institutional providers of health care services"; and

(ii) by inserting after paragraph (6) the following new paragraph:

"(7) A Professional Standards Review Organization located in a State has the function and duty to assume responsibility for the review under paragraph (1) of professional activities in intermediate care facilities (as defined in section 1905(c)) and in public institutions for the mentally retarded (described in section 1905(d)(1) only if the Secretary finds, on the basis of such documentation as he may require from the State, that the single State agency which administers or supervises the administration of the State plan approved under title XIX for that State is not performing effective review of the quality and necessity of health care services provided in such facilities and institutions.".

(e) Section 1160(b)(1) of such Act is amended by striking out "practitioner or provider" each time it appears therein and inserting in lieu thereof "health care practitioner or hospital, or other health care facility, agency, or organization".

(f) Section 1163(a)(2) of such Act is amended to read as follows:

"(2) Members of the Council shall be appointed for a term of three years, except that of the members appointed in 1979, four shall be appointed for a term of only two years, and three for a term of only only one year. Members of the Council shall be eligible for reappointment.".

(g) Section 1163 of such Act is amended by striking out subsection (f).

(h) Section 1166 of such Act is amended—

(1) by striking out "or (2)" in subsection (a) and inserting in lieu thereof ", (2)";

(2) by inserting the following immediately before the period at the end of subsection (a): ", or (3) in accordance with subsection (b)";

(3) by redesignating subsection (b) as subsection (c);

(4) by inserting the following new subsection immediately after subsection (a):

"(b) A Professional Standards Review Organization shall provide, in accordance with procedures established by the Secretary, data and information—

"(1) to assist Federal and State agencies recognized by the Secretary as having responsibility for identifying

and investigating cases or patterns of fraud or abuse, which data and information shall be provided by such Organization to such agencies at the request of such agencies at the discretion of such Organization on the basis of its findings with respect to evidence of fraud or abuse;

"(2) to assist the Secretary, and such Federal and State agencies recognized by the Secretary as having health planning or related responsibilities under Federal or State law (including health systems agencies and State health planning and development agencies), in carrying out appropriate health care planning and related activities, which data and information shall be provided in such format and manner as may be prescribed by the Secretary or agreed upon by the responsible Federal and State agencies and such Organization, and shall be in the form of aggregate statistical data (without identifying any individual) on a geographic, institutional, or other basis reflecting the volume and frequency of services furnished, as well as the demographic characteristics of the population subject to review by such Organization.

The penalty provided in subsection (c) shall not apply to the disclosure of any data and information received under this subsection, except that such penalty shall apply to the disclosure (by the agency receiving such data and information) of any such data and information described in paragraph (1) unless such disclosure is made in a judicial, administrative, or other formal legal proceeding resulting from an investigation conducted by the agency receiving the data and information."; and

(5) by inserting after subsection (c) (as so redesignated) the following new subsection:

"(d) No patient record in the possession of a Professional Standards Review Organization, a Statewide Professional Standards Review Council, or the National Professional Standards Review Council shall be subject to subpena or discovery proceedings in a civil action.".

(i) Section 1167 of such Act is amended by adding the following new subsection at the end thereof:

"(d) The Secretary shall make payment to a Professional Standards Review Organization, whether conditionally designated or qualified, or to any member or employee thereof, or to any person who furnishes legal counsel or services to such organization, in an amount equal to the reasonable amount of the expenses incurred, as determined by the Secretary, in connection with the defense of any suit, action, or proceeding brought against such organization, member or employee related to the performance of any duty or function of such organization, member or employee (as described in section 1155).".

(j) Section 1168 of such Act is amended by adding at the end thereof the following new sentence: "The Secretary shall make payments to Professional Standards Review Orga-

nizations (whether designated on a conditional basis or otherwise) from funds described in the first sentence of this section (without any requirement for the contribution of funds by any State or political subdivision thereof) for expenses incurred in the performance of duties by such Oganizations.".

(k) Part B of title XI of such Act (as amended by subsection (d)(2)(D) of this section) is further amended by adding after section 1171 the following new section:

"ANNUAL REPORTS

"SEC. 1172. The Secretary shall submit to the Congress not later than April 1, 1978, and not later than April 1 of each year thereafter, a full and complete report on the administration, impact, and cost of the program under this part during the preceding fiscal year, including data and information on—

"(1) the number, status (conditional or otherwise), and service areas of, and review methodologies employed by, all Professional Standards Review Organizations participating in the program;

"(2) the number of health care institutions and practitioners whose services are subject to review by Professional Standards Review Organizations, and the number of beneficiaries and recipients who received services subject to such review during such year;

"(3) services determined, in accordance with the provisions of this part, to have been (A) medically unnecessary, (B) furnished in an inappropriate setting, or (C) deficient in quality;

"(4) the imposition of penalties and sanctions under this title for violations of law and for failure to comply with the obligations imposed by this part;

"(5) the total costs incurred under titles V, XI, XVIII, and XIX of this Act in the implementation and operation of all procedures required by such titles for the review of services to determine their medical necessity, appropriateness of use, and quality;

"(6) changes in utilization rates and patterns, and changes in medical procedures and practices, attributable to the activities of Professional Standards Review Organizations;

"(7) the progress being made among Professional Standards Review Organizations in adopting and implementing the ambulatory care review methodologies developed under section 1155(g)(1);

"(8) the results of program evaluation activities, including the operation of data collection systems and the status of Professional Standards Review Organization data policy and implementation;

"(9) the extent to which Professional Standards Review Organizations are performing reviews of services

for other governmental or private health insurance programs; and

"(10) recommendations for legislative changes.".

2. On page 27, insert after line 7 the following new subsection:

(l) (1) Section 1166 of such Act (as amended by subsection (h)) is further amended by adding after subsection (d) the following new subsection:

"(e) (1) No officer, employee, or agent of a Professional Standards Review Organization may disclose to any officer, employee, or agent of the Federal Government, and no officer, employee, or agent of the Federal Government may inspect (or have access to), any part of an individually identifiable medical record (as defined in paragraph (3)) of a patient which—

"(A) is in the possession of a Professional Standards Review Organization, and

"(B) relates to medical care which is not provided directly by the Federal Government or is not paid for (in whole or in part) under a Federal program or under a program receiving Federal financial assistance.

unless the patient has authorized such disclosure and inspection in accordance with paragraph (2).

"(2) A patient authorizes disclosure and inspection of a medical record for purposes of paragraph (1) only if, in a signed and dated statement, he—

"(A) authorizes the disclosure and inspection for a specific period of time;

"(B) identifies the medical record authorized to be disclosed and inspected;

"(C) specifies the purposes for which the record may be disclosed and inspected; and

"(D) specifies the agencies which may inspect the record and to which the record may be disclosed.

"(3) For purposes of this subsection:

"(A) The term 'individually identifiable medical record' means a medical, psychiatric, or dental record concerning an individual that is in a form which either identifies the individual or permits identification of the individual through means (whther direct or indirect) available to the public.

"(B) The term 'medical care' includes medical, psychiatric, and dental care and treatment.".

(2) After taking into consideration the recommendations contained in the final report of the Privacy Protection Study Commission (established under section 5 of the Privacy Act of 1974), the Secretary of Health, Education, and Welfare shall prepare and submit, not later than three months after the date such Commission submits its final report, to the Committee on Interstate and Foreign Commerce and the Committee on Ways and Means of the House of Representatives and to the Committee on Human Resources and the Committee on Finance of the Senate a report containing specific recommendations (including draft legislation) for the timely devel-

opment and implementation of appropriate procedures (including use of detailed written consent forms) in order to (A) maintain the confidentiality of individually identifiable medical records (whether they relate to medical care provided directly by, or through the financial assistance of, the Federal Government or not), and (B) prevent the unwarranted inspection by, and disclosure to, Federal officers, employees, and agents and Professional Standards Review Organizations of such records.

3. On page 27, strike out line 8 and all that follows through line 21 on page 35 and insert in lieu thereof the following:

(m)(1) Title XI of such Act (as amended by subsections (d)(2)(D) and (k) of this section) is further amended by adding after section 1172 the following new section:

"MEDICAL OFFICERS IN AMERICAN SAMOA, THE NORTHERN MARIANA ISLANDS, AND THE TRUST TERRITORY OF THE PACIFIC ISLANDS TO BE INCCLUDED IN THE PROFESSIONAL STANDARDS PROGRAM

"SEC. 1173. For purposes of applying this part (except sections 1155(c) and 1163) to American Samoa, the Northern Mariana Islands, and the Trust Territory of the Pacific Islands, individuals licensed to practice medicine in those places shall be considered to be physicians and doctors of medicine.".

(2) The second sentence of section 1101(a)(1) of such Act is amended by inserting "and in part B of this title" after "title V".

(n) Section 1861(w)(2) of such Act is amended by inserting "part B of this title or under" immediately after "entitled to have payment made for such services under".

(o) Section 1167 of such Act is amended—

(1) by inserting "or to any Statewide Professional Standards Review Council" in subsection (a) after "Professional Standards Review Organization";

(2) by inserting "or such Council" in subsection (a) after "such Organization";

(3) by inserting "or of any Statewide Professional Standards Review Council" in subsection (b)(1) after "Professional Standards Review Organization";

(4) by inserting "or council" in subsection (b)(1) after "organization";

(5) by inserting "or of Statewide Professional Standards Review Councils" in subsection (b)(1) after "Review Organizations"; and

(6) by inserting "AND STATEWIDE PROFESSIONAL STANDARDS REVIEW COUNCILS" in the heading of the section after "PROFESSIONAL STANDING REVIEW ORGANIZATIONS".

(p)(1) Section 1152(b)(1)(A) of such Act is amended by striking out "subsection (c)(i)" and inserting in lieu thereof "subsection (c)(1)".

(2) Section 1155(a)(1) of such Act is amended by striking out "(subject to the provisions of subsection (g))" in the matter preceding subparagraph (A).

(3) Section 1160(b)(1) of such Act is amended by inserting "or" after "permanently" in the matter following subparagraph (B).

ISSUANCE OF SUBPENAS BY COMPTROLLER GENERAL

SEC. 6. Part A of title XI of the Social Security Act is amended by inserting after section 1124 (added by section 3(a) of this Act) the following new section:

"ISSUANCE OF SUBPENAS BY COMPTROLLER GENERAL

"SEC. 1125. (a) For the purpose of any audit, investigation, examination, analysis, review, evaluation, or other function authorized by law with respect to any program authorized under section 226, titles V, XVIII, or XIX or part B of this title of this Act, the Comptroller General of the United States shall have power to sign and issue subpenas to any person requiring the production of any pertinent books, records, documents, or other information. Subpenas so issued by the Comptroller General shall be served by anyone authorized by him (1) by delivering a copy thereof to the person named therein, or (2) by registered mail or by certified mail addressed to such person at his last dwelling place or principal place of business. A verified return by the person so serving the subpena setting forth the manner of service, or, in the case of service by registered mail or by certified mail, the return post office receipt therefor signed by the person so served, shall be proof of service.

"(b) In case of contumacy by, or refusal to obey a subpena issued pursuant to subsection (a) of this section and duly served upon, any person, any district court of the United States for the judicial district in which such person charged with contumacy or refusal to obey is found, or resides or transacts business, upon application by the Comptroller General, shall have jurisdiction to issue on order requirin such person to produce the books, records, documents, or other information sought by the subpena; and any failure to obey such order of the court may be punished by the court as a contempt thereof. In proceedings brought under this subsection, the Comptroller General may be represented by attorneys employed in the General Accounting Office or by counsel whom he may employ without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and the provisions of chapter 51 and subchapters III and VI of chapter 53 of such title relating to classification and General Schedule pay rates.

"(c)(1) Except as provided in paragraph (2), any employee or officer of the General Accounting Office who dis-

closes a personal medical record (defined in paragraph (3)) to any person, other than an employee or officer of such Office whose official duties require disclosure of such information, shall be fined not more than $1,000 or imprisoned for not more than six months, or both, and charged the costs of prosecution.

"(2) An employee or officer of the General Accounting Office who discloses a personal medical record to a Federal or State agency recognized by the Secretary as having responsibility for identifying and investigating cases or patterns of fraud or abuse shall not be subject to the penalties of paragraph (1) if the Comptroller General has determined before the disclosure of such record that the record reveals evidence of fraud or abuse.

"(3) For the purposes of this section, the term 'personal medical record' means data or information—

"(A) relating to the medical or mental condition or treatment of any individual;

"(B) acquired by any employee or officer of the General Accounting Office in the course of any audit, investigation, examination, analysis, review, evaluation, or other fuction authorized by law with respect to any program authorized under section 226, title V, XVIII, or XIX, or part B of this title of this Act; and

"(C) in a form which can be associated with, or otherwise identify, directly or indirectly, the individual described in subparagraph (A).

"(d) No personal medical record in the possession of the General Accounting Office shall be subject to subpena or discovery proceedings in a civil action.".

SUSPENSION OF PRACTITIONERS CONVICTED OF MEDICARE- OR MEDICAID-RELATED CRIMES

SEC. 7. (a) Section 1862 of the Social Security Act is amended by adding at the end thereof the following new subsection:

"(e)(1) Whenever the Secretary determines that a physician or other individual practitioner has been convicted (on or after the date of the enactment of this subsection, or within such period prior to that date as the Secretary shall specify in regulations) of a criminal offense related to such physician's or practitioner's involvement in the program under this title or the program under title XIX, the Secretary shall suspend such physician or practitioner from participation in the program under this title for such period as he may deem appropriate; and no payment may be made under this title with respect to any item or service furnished by such physician or practitioner during the period of such suspension. The provisions of paragraphs (2) and (3) of subsection (d) shall apply with respect to determinations made by the Secretary under this subsection.

"(2) In any case where the Secretary under paragraph (1) suspends any physician or other individual practitioner from participation in the program under this title, he shall—

"(A) promptly notify each single State agency which administers or supervises the administration of a State plan approved under title XIX of the fact, circumstances, and period of such suspension; and

"(B) promptly notify the appropriate State or local agency or authority having responsibility for the licensing or certification of such physician or practitioner of the fact and circumstances of such suspension, request that appropriate investigations be made and sanctions invoked in accordance with applicable State law and policy, and request that such State or local agency or authority keep the Secretary and the Inspector General of the Department of Health, Education, and Welfare fully and currently informed with respect to any actions taken in response to such request.".

(b) Section 1902(a) of such Act (as amended by sections 2(b) and 3(c) of this Act) is amended—

(1) by striking out "and" at the end of paragraph (37);

(2) by striking out the period at the end of paragraph (38) and inserting in lieu thereof "; and "; and

(3) by inserting after paragraph (38) the following new paragraph:

"(39) provide that, subject to subsection (g), whenever the single State agency which administers or supervises the administration of a State plan approved under title XIX is notified by the Secretary under section 1862(e)(2)(A) that a physician or other individual practitioner has been suspended from participation in the program under title XVIII, the agency shall promptly suspend such physician or practitioner from participation in its plan under this title for not less than the period specified in such notice, and no payment may be made under its plan with respect to any items or service furnished by such physician or practitioner during the period of the suspension under this title.".

(c) Section 1902 of such Act is amended by adding after subsection (f) the following new subsection:

"(g) The Secretary may waive suspension under subsection (a)(39) of a physician's or practitioner's participation in an State plan approved under this title and of the prohibition under such subsection of payment for items or services furnished by him during the period of such suspension, if the single State agency which administers or supervises the administration of a State plan approved under title XIX such plan submits a request to the Secretary for such waiver and if the Secretary approves such request.".

(d) Section 332(c) of the Public Health Service Act (relating to considerations in the designation of health manpower shortage areas) (as added by section 407 of the Health Pro-

fessions Educational Assistance Act of 1976) is amended by inserting after paragraph (2) the following new paragraph:

"(3) The extent to which individuals who are (A) residents of the area, members of the population group, or patients in the medical facility or other public facility under consideration for designation, and (B) entitled to have payment made for medical services under title XVIII or XIX of the Social Security Act, cannot obtain such services because of suspension of physicians from the programs under such titles.".

(e) (1) The amendments made by this section shall apply with respect to determinations and designations made on and after the date of the enactment of this Act.

(2) The amendment made by subsection (b) shall become effective on October 1, 1977.

DISCLOSURE OF PROVIDERS OF OWNERS AND CERTAIN OTHER INDIVIDUALS CONVICTED OF CERTAIN OFFENSES

SEC. 8. (a) Part A of title XI of the Social Security Act is amended by inserting after section 1125 (added by section 6 of this Act) the following new section:

"DISCLOSURE BY INSTITUTIONS, ORGANIZATIONS, AND AGENCIES OF OWNERS AND CERTAIN OTHER INDIVIDUALS WHO HAVE BEEN CONVICTED OF CERTAIN OFFENSES

"SEC. 1126. (a) As a condition of participation in or certification or recertification under the programs established by titles XVIII, XIX, and XX, any hospital, nursing facility, or other institution, organization, or agency shall be required to disclose to the Secretary or to the appropriate State agency the name of any person who—

"(1) has a direct or indirect ownership or control interest of 5 percent or more in such institution, organization, or agency or is an officer, director, agent, or managing employee (as defined in subsection (b)) of such institution, organization, or agency, and

"(2) has been convicted (on or after the date of the enactment of this section, or within such period prior to that date as the Secretary shall specify in regulations) of a criminal offense related to the involvement of such person in any of such programs.

The Secretary or the appropriate State agency shall promptly notify the Inspector General in the Department of Health, Education, and Welfare of the receipt from any institution, organization, or agency of any application or request for such participation, certification, or recertification which discloses the name of any such person, and shall notify the Inspector General of the action taken with respect to such application or request.

"(b) For the purposes of this section, the term 'managing employee' means, with respect to an institution, organization, or agency, an individual, including a general manager, busi-

ness manager, administrator, and director, who exercises operational or managerial control over the institution, organization, or agency, or who directly or indirectly conducts the day-to-day operations of the institution, organization, or agency.".

(b)(1) Section 1866(a) of such Act is amended by adding at the end thereof the following new paragraph:

"(3) The Secretary may refuse to enter into or renew an agreement under this section with a provider of services if any person who has a direct or indirect ownership or control interest of 5 percent or more in such provider, or who is an officer, director, agent, or managing employee (as defined in section 1126(b)) of such provider, is a person described in section 1126(a).".

(2) Section 1866(b)(2) of such Act is amended by inserting before the period at the end thereof the following: ", or (G) that such provider (at the time the agreement was entered into) did not fully and accurately make any disclosure required of it by section 1126(a)".

(c) Section 1903 of such Act is amended by adding after subsection (m) the following new subsection:

"(n) The State agency may refuse to enter into any contract or agreement with a hospital, nursing home, or other institution, organization, or agency for purposes of participation under the State plan, or otherwise to approve an institution, organization, or agency for such purposes, if any person who has a direct or indirect ownership or control interest of 5 percent or more in such institution, organization, or agency, or who is an officer, director, agent, or managing employee (as defined in section 1126(b)) of such institution, organization, or agency, is a person described in section 1126(a) (whether or not such institution, organization, or agency has in effect an agreement entered into with the Secretary pursuant to section 1866 or is subject to a suspension of payment order issued under subsection (j) of this section); and notwithstanding any other provision of this section, the State agency may terminate any such contract, agreement, or approval if it determines that the institution, organization, or agency did not fully and accurately make any disclosure required of it by section 1126(a) at the time such contract or agreement was entered into or such approval was given.".

(d) Section 2002(a) of such Act is amended by adding at the end thereof the following new paragraph:

"(15) Any State may refuse to enter into a contract or other arrangement with a provider of services for purposes of participation under the program established by this title, or otherwise to approve a provider for such purposes, if any person who has a direct or indirect ownership or control interest of 5 percent or more in such provider, or who is an officer, director, agent, or managing employee (as defined in section 1126(b)) of such provider, is a person described in section 1126(a), and may terminate any such contract, arrangement, or approval if it determines that the provider

did not fully and accurately make any disclosure required of it by section 1126(a) at the time the contract or arrangement was entered into or the approval was given.".

(e) The amendments made by this section shall apply with respect to contracts, agreements, and arrangements entered into and approvals given pursuant to applications or requests made on and after the first day of the fourth month beginning after the date of the enactment of this Act.

FEDERAL ACCESS TO RECORDS

SEC. 9. Section 1902(a)(27)(B) of the Social Security Act is amended by inserting "or the Secretary" after "State agency" each place it appears.

CLAIMS PROCESSING AND INFORMATION RETRIEVAL SYSTEMS FOR MEDICAID PROGRAMS

SEC. 10. (a) Section 1903(a)(3)(B) of the Social Security Act is amended by striking out "notice to each individual who is furnished services covered by the plan of the specific services so covered" and inserting in lieu thereof "notice to each individual who is furnished services covered by the plan, or to each individual in a sample group of individuals who are furnished such services, of the specific services (other than confidential services) so covered".

(b) The amendment made by subsection (a) shall apply with respect to calendar quarters beginning after the date of the enactment of this Act.

RESTRICTION OF FEDERAL MEDICAID PAYMENTS

SEC. 11. (a) Section 1903 of the Social Security Act is amended by adding after subsection (n) (added by section 8(c) of this Act) the following new subsection:

"(o) Notwithstanding the preceding provisions of this section, no payment shall be made to a State under the preceding provisions of this section for expenditures for medical assistance provided for an individual under its State plan approved under this title to the extent that a private insurer (as defined by the Secretary by regulation) would have been obligated to provide such assistance but for a provision of its insurance contract which has the effect of limiting or excluding such obligation because the individual is eligible for or is provided medical assistance under the plan.".

(b) The amendment made by subsection (a) shall apply with respect to medical assistance provided under a State plan approved under title XIX of the Social Security Act, on and after January 1, 1978.

STUDY AND REVIEW OF MEDICARE CLAIMS PROCESSING

SEC. 12. The Comptroller General of the United States shall conduct a comprehensive study and review of the administrative structure established for the processing of claims

under title XVIII of the Social Security Act, for the purpose of determining whether and to what extent more efficient claims administration under such title could be achieved—

(1) by reducing the number of participating intermediaries and carriers;

(2) by making a single organization responsible for the processing of claims, under both part A and part B of such title, in a particular geographic area;

(3) by providing for the performance of claims processing functions on the basis of a prospective fixed price;

(4) by providing incentive payments for the most efficient organizations; or

(5) by other modifications in such structure and related procedures.

The Comptroller General shall submit to the Congress no later than July 1, 1979, a complete report setting forth the results of such study and review, together with his findings and his recommendations with respect thereto.

ABOLITION OF PROGRAM REVIEW TEAMS UNDER MEDICARE

SEC. 13. (a) Section 1862(d) of the Social Security Act is amended by striking out paragraph (4).

(b)(1) Section 1862(d)(1)(B) of such Act is amended by striking out ", with the concurrence of the appropriate program review team appointed pursuant to paragraph (4),".

(2) Section 1862(d)(1)(C) of such Act is amended to read as follows:

"(C) has furnished services or supplies which are determined by the Secretary, on the basis of reports transmitted to him in accordance with section 1157 of this Act (or, in the absence of any such report, on the basis of such data as he acquires in the administration of the program under this title), to be substantially in excess of the needs of individuals or to be of a quality which fails to meet professionally recognized standards of health care.".

(3) Clause (F) of section 1866(b)(2) of such Act is amended to read as follows: "(F) that such provider has furnished services or supplies which are determined by the Secretary to be substantially in excess of the needs of individuals or to be of a quality which fails to meet professionally recognized standards of health care".

(4) Section 1157 of such Act is amended by striking out the last sentence.

(c) The amendments made by this section shall take effect on the date of the enactment of this Act.

AMENDMENTS RELATING TO FISCAL INTERMEDIARIES

SEC. 14. (a) Section 1816 of the Social Security Act is amended—

(1) by inserting "(and to providers assigned to such agency or organization under subsection (e))" in the first

sentence of subsection (a) after "to such providers" the second and third times it appears;

(2) by amending subsection (b) to read as follows:

"(b) The Secretary shall not enter into or renew an agreement with any agency or organization under this section unless—

"(1) he finds—

"(A) after applying the standards, criteria, and procedures developed under subsection (f), that to do so is consistent with the effective and efficient administration of this part, and

"(B) that such agency or organization is willing and able to assist the providers to which payments are made through it under this part in the application of safeguards against unnecessary utilization of services furnished by them to individuals entitled to hospital insurance benefits under section 226, and the agreement provides for such assistance; and

"(2) such agency or organization agrees—

"(A) to furnish to the Secretary such of the information acquired by it in carrying out its agreement under this section, and

"(B) to provide the Secretary with access to all such data, information, and claims processing operations,

as the Secretary may find necessary in performing his functions under this part.";

(3) by inserting "after applying the standards, criteria, and procedures developed under subsection (f) and" in subsection (e)(2) before "after reasonable notice";

(4) by redesignating subsections (e), (f), and (g) as subsections (g), (h), and (i), respectively; and

(5) by inserting after subsection (d) the following new subsections:

"(e)(1) Notwithstanding subsections (a) and (d), the Secretary, after taking into consideration any preferences of providers of services, may assign or reassign any provider of services to any agency or organization which has entered into an agreement with him under this section, if he determines, after applying the standards, criteria, and procedures developed under subsection (f), that such assignment or reassignment would result in the more effective and efficient administration of this part.

"(2) Notwithstanding subsections (a) and (d), the Secretary may designate a national or regional agency or organization which has entered into an agreement with him under this section to perform functions under the agreement with respect to a class of providers of services in the Nation or region (as the case may be), if he determines, after applying the standards, criteria, and procedures developed under subsection (f), that such designation would result in more effective and efficient administration of this part.

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"(3)(A) Before the Secretary makes an assignment or reassignment under paragraph (1) of a provider or services to other than the agency or organization nominated by the provider, he shall furnish (i) the provider and such agency or organization with a full explanation of the reasons for his determination as to the efficiency and effectiveness of the agency or organization to perform the functions required under this part with respect to the provider, and (ii) such agency or organization with opportunity for a hearing, and such determination shall be subject to judicial review in accordance with chapter 7 of title 5, United States Code.

"(B) Before the Secretary makes a designation under paragraph (2) with respect to a class of providers of services, he shall furnish (i) such providers and the agencies and organizations adversely affected by such designation with a full explanation of the reasons for his determination as to the efficiency and effectiveness of such agencies and organizations to perform the functions required under this part with respect to such providers, and (ii) the agencies and organizations adversely affected by such designation with opportunity for a hearing, and such determination shall be subject to judicial review in accordance with chapter 7 of title 5, United States Code.

"(f) In order to determine whether the Secretary should enter into, renew, or terminate an agreement under this section with an agency or organization, whether the Secretary should assign or reassign a provider of services to an agency or organization, and whether the Secretary should designate an agency or organization to perform services with respect to a class of providers of services, the Secretary shall develop standards, criteria, and procedures to evaluate such agency's or organization's (1) overall performance of claims processing and other related functions required to be performed by such an agency or organization under an agreement entered into under this section, and (2) performance of such functions with respect to specific providers of services.".

(b) The Secretary of Health, Education, and Welfare shall develop the standards, criteria, and procedures described in subsection (f) of section 1816 of the Social Security Act (as added by subsection (a)(5) not later than October 1, 1978.

(c) The amendment made by paragraphs (2) and (3) of subsection (a) to the extent that they require application of standards, criteria, and procedures developed under section 1816(f) of the Social Security Act shall apply to the entering into, renewal, or termination of agreements on and after October 1, 1978.

(d) Except as provided in subsection (c), the amendment made by subsection (a)(2) shall apply to agreements entered into or renewed on or after the date of enactment of this Act.

DISCLOSURE BY PROVIDERS OF THE HIRING OF CERTAIN FORMER EMPLOYEES OF FISCAL INTERMEDIARIES

SEC. 15. (a) Section 1866(a)(1) of the Social Security Act is amended—

(1) by striking out the period at the end of subparagraph (C) and inserting in lieu thereof ", and"; and

(2) by inserting after subparagraph (C) the following new subparagraph:

"(D) to promptly notify the Secretary of its employment of an individual who, at any time during the year preceding such employment, was employed in a managerial, accounting, auditing, or similar capacity (as determined by the Secretary by regulation) by an agency or organization which serves as a fiscal intermediary or carrier (for purposes of part A or part B, or both, of this title) with respect to the provider.".

(b) The amendments made by subsection (a) shall apply with respect to agreements entered into or renewed on and after the date of enactment of this Act.

PAYMENT FOR DURABLE MEDICAL EQUIPMENT

SEC. 16. (a) Section 1833(f) of the Social Security Act is amended to read as follows:

"(f)(1) In the case of durable medical equipment to be furnished an individual as described in section 1861(s)(6), the Secretary shall determine, on the basis of such medical and other evidence as he finds appropriate (including certification by the attending physician with respect to expected duration of need), whether the expected duration of the medical need for the equipment warrants a presumption that purchase of the equipment would be less costly or more practical than rental. If the Secretary determines that such a presumption does exist, he shall require that the equipment be purchased, on a lease-purchase basis or otherwise, and shall make payment in accordance with the lease-purchase agreement (or in a lump sum amount if the equipment is purchased other than on a lease-purchase basis); except that the Secretary may authorize the rental of the equipment notwithstanding such determination if he determines that the purchase of the equipment would be inconsistent with the purposes of this title or would create an undue financial hardship on the individual who will use it.

"(2) With respect to purchases of used durable medical equipment, the Secretary may waive the 20 percent coinsurance amount applicable under subsection (a) whenever the purchase price of the used equipment is at least 25 percent less than the reasonable charge for comparable new equipment.

"(3) For purposes of paragraph (1), the Secretary may, pursuant to agreements made with suppliers of durable medical equipment, establish reimbursement procedures which he finds to be equitable, economical, and feasible.

"(4) The Secretary shall encourage suppliers of durable medical equipment to make their equipment available to individauls entitled to benefits under this title on a lease-purchase basis whenever possible.".

(b) The amendment made by subsection (a) shall apply with respect to durable medical equipment purchased or rented on or after October 1, 1977.

FUNDING OF STATE MEDICAID FRAUD CONTROL UNITS

SEC. 17. (a) Section 1903(a) of the Social Security Act (as amended by section2(b)(2) of this Act) is amended by redesignating paragraph (7) as paragraph (8) and by inserting after paragraph (6) the following new paragraph:

"(7) subject to subsection (b)(3), an amount equal to 90 per centum of the sums expended during each quarter beginning on or after October 1, 1977, and ending before October 1, 1980, with respect to costs incurred during such quarter (as found necessary by the Secretary for the elimination of fraud in the provision and administration of medical assistance provided under the State plan) which are attributable to establishment and operation of (including the training of personnel employed by) a State medicaid fraud control unit (described in subsection (p)); plus".

(b) Section 1903(b) of such Act is amended by inserting after paragraph (2) the following new paragraph:

"(3) The amount of funds which the Secretary is otherwise obligated to pay a State during a quarter under subsection (a)(7) may not exceed the higher of—

"(A) $125,000, or

"(B) one-quarter of 1 per centum of the sums expended by the Federal, State, and local governments during the previous quarter in carrying out the State's plan under this title.".

(c) Section 1903 of such Act is further amended by inserting after subsection (o) (added by section 11(a) of this Act) the following new subsection:

"(p) For the purposes of this section, the term 'State medicaid fraud control unit' means a single identifiable entity of the State government which the Secretary certifies (and annually recertifies) as meeting the following requirements:

"(1) The entity either (A) is a unit of the office of the State Attorney General or of another department of State government which possesses statewide authority to prosecute individuals for criminal violations, or (B) is in a State the constitution of which does not provide for the criminal prosecution of individuals by a statewide authority and has formal procedures, approved by the Secretary, which (i) assure its referral of suspected criminal violations relating to the program under this title to the appropriate authority or authorities in the

State for prosecution and (ii) assure its assistance of, and coordination with, such authority or authorities in such prosecutions.

"(2) The entity is separate and distinct from the single State agency that administers or supervises the administration of the State plan under this title.

"(3) The entity's function is conducting a statewide program for the investigation and prosecution of violations of all applicable State laws regarding any and all aspects of fraud in connection with any aspect of the provision of medical assistance and the activities of providers of such assistance under the State plan under this title.

"(4) The entity has procedures for reviewing complaints of the abuse and neglect of patients of health care facilities which receive payments under the State plan under this title, and, where appropriate, for acting upon such complaints under the criminal laws of the State or for referring them to other State agencies for action.

"(5) The entity provides for the collection, or referral for collection to a single State agency, of overpayments made under the State plan to health care facilities and discovered by the entity in carrying out its activities.

"(6) The entity employs such auditors, attorneys, investigators, and other necessary personnel and is organized in such a manner as is necessary to promote the effective and efficient conduct of the entity's activities.

"(7) The entity submits to the Secretary an application and annual reports containing such information as the Secretary determines, by regulation, to be necessary to determine whether the entity meets the other requirements of this subsection.".

(d)(1) The amendment made by subsection (a) shall apply with respect to calendar quarters beginning after September 30, 1977.

(2) The Secretary of Health, Education, and Welfare shall establish such regulations, not later than ninety days after the date of enactment of this Act, as are necessary to carry out the amendments made by this section.

REPORT ON HOME HEALTH AND OTHER IN-HOME SERVICES

SEC. 18. (a) Not later than one year after the date of enactment of this Act, the Secretary of Health, Education, and Welfare shall submit to the appropriate committees of the Congress a report analyzing, evaluating, and making recommendations with respect to, all aspects (including the availability, administration, provision, reimbursement procedures, and cost) of the delivery of home health and other in-home services authorized to be provided under titles XVIII, XIX, and XX of the Social Security Act.

(b) Such report shall include an evaluation of the coordination of such services provided under different

titles, and shall also include recommendations for changes in regulations and legislation with respect to—

(1) the scope and definition of such services provided under such titles;

(2) the requirements for an individual to be eligible to receive such services under such titles;

(3) the standards for certification of providers of such services under such titles and (as appropriate) the uniformity of such standards for the programs under the different titles;

(4) procedures for control of utilization and assurance of quality of such services under such titles, including (as appropriate) the licensing and accreditation of agencies providing such services, a certification of need program with respect to the offering of such services, and the development and use of norms and standards for review of the utilization and quality of such services;

(5) methods of reimbursement for such services, including (A) methods of comparing costs incurred by providers of such services in order to determine the reasonableness of such costs, and (B) methods which provide for more uniform reimbursement procedures under titles XVIII and XIX of the Social Security Act; and

(6) the prevention of fraud and abuse in the delivery of such services under such titles,

the reasons for such recommendations, an analysis of the impact of implementing such recommendations on the cost of such services and the demand for such services, and the methods of financing any recommended increased provision of such services under such titles.

(c) In developing the report the Secretary shall consult with professional organizations, experts, and individual health professionals in the field of home health and other in-home services and with providers, private insurers, and consumers of such services.

ESTABLISHMENT OF UNIFORM REPORTING SYSTEMS FOR DIFFERENT TYPES OF HEALTH SERVICES FACILITIES AND ORGANIZATIONS; MAKING OF REPORTS UNDER MEDICARE AND MEDICAID PROGRAMS IN ACCORDANCE WITH SUCH SYSTEMS

SEC. 19. (a) Part A of title XI of this Social Security Act is amended by inserting after section 1120 the following new section:

"UNIFORM REPORTING SYSTEMS FOR HEALTH SERVICES FACILITIES AND ORGANIZATIONS

"SEC. 1121. (a) For the purposes of reporting the cost of services provided by, of planing, and of measuring and comparing the efficiency of and effective use of services in, hospitals, skilled nursing facilities, intermediate care facilities, home health agencies, health maintenance organizations, and other types of health services facilities and organizations to which payment may be made under this Act, the Secre-

tary shall establish by regulation, for each such type of health services facility or organization, a uniform system for the reporting by a facility or organization of that type of the following information:

"(1) The aggregate cost of operation and the aggregate volume of services.

"(2) The costs and volume of services for various functional accounts and subaccounts.

"(3) Rates, by category of patient and class of purchaser.

"(4) Capital assets, as defined by the Secretary, including (as appropriate) capital funds, debt service, lease agreements used in lieu of capital funds, and the value of land, facilities, and equipment.

"(5) Discharge and bill data.

The uniform reporting system for a type of health services facility or organization shall provide for apropriate variation in the application of the system to different classes of facilities or organizations within that type and shall be established, to the extent practicable, consistent with the cooperative system for producing comparable and uniform health information and statistics described in section 306(e)(1) of the Public Health Service Act.

"(b) The Secretary shall—

"(1) monitor the operation of the systems established under subsection (a);

"(2) assist with and support demonstrations and evaluations of the effectiveness and cost of the operation of such systems and encourage State adoption of such systems; and

"(3) periodically revise such systems to improve their effectiveness and diminish their cost.

"(c) The Secretary shall provide information obtained through use of the uniform reporting system described in subsection (a) in a useful maner and format to appropriate agencies and organizations, including health systems agencies (designated under section 1515 of the Public Health Service Act) and State health planning and develompent agencies (designated under section 1521 of such Act), as may be necessary to carry out such agencies' and organizations' functions.".

(b)(1) Section 1861(v)(1) of the Social Security Act is amended by adding after subparagraph (E) the following new subparagraph:

"(F) Such regulations shall require each provider of services (other than a fund) to make reports to the Secretary of information described in section 1121(a) in accordance with the uniform reporting system (established under such section) for that type of provider.".

(2) Section 1902(a) of such Act (as amended by sections 2(b), 3(c), and 7(b) of this Act) is amended—

(A) by striking out "and" at the end of paragraph (38);

(B) by striking out the period at the end of paragraph (39) and inserting in lieu thereof "; and"; and

(C) by inserting after paragraph (39) the following new paragraph:

"(40) require each health services facility or organization which receives payments under the plan and of a type for which a uniform reporting system has been established under section 1121(a) to make reports to the Secretary of information described in such section in accordance with the uniform reporting system (established under such section) for that type of facility or organization.".

(c)(1) The Secretary of Health, Education, and Welfare shall establish the systems described in section 1121(a) of the Social Security Act (added by subsection (a) of this section) only after consultation with interested parties and—

(A) for hospitals, skilled nursing facilities, and intermediate care facilities, not later than the end of the one-year period, and

(B) for other types of health services facilities and organizations, not later than the end of the two-year period, beginning on the date of enactment of this Act.

(2)(A) The amendments made by subsection (b) shall apply, with respect to operations of a hospital, skilled nursing facility, or intermediate care facility, on and after the first day of its first fiscal year which begins after the end of the six-month period beginning on the date a uniform reporting system is established (under section 1121(a) of the Social Security Act) for that type of health services facility.

(B) The amendments made by subsection (b) shall apply, with respect to the operation of a health services facility or organization which is neither a hospital, a skilled nursing facility, nor an intermediate care facility, on and after the first day of its first fiscal year which begins after such date as the Secretary of Health, Education, and Welfare determines to be appropriate for the implementation of the reporting requirement for that type of facility or organization.

(C) Except as provided in subparagraphs (A) and (B), the amendments made by subsection (b)(2) shall apply, with respect to State plans approved under title XIX of the Social Security Act, on and after October 1, 1977.

4. On page 35, add after line 21 the following new section:

DELAY IN, AND WAIVER OF, IMPOSITION OF REDUCTION OF FEDERAL MEDICAL ASSISTANCE PERCENTAGE DUE TO A STATE'S FAILURE TO HAVE AN EFFECTIVE MEDICAID UTILIZATION CONTROL PROGRAM

SEC. 20. (a) Section 1903(g) of the Social Security Act is amended—

(1) by striking out "With respect to" in the first sentence of paragraph (1) and inserting in lieu thereof "Subject to paragraph (3), with respect to";

(2) by inserting "timely" in paragraph (2) before "sample onsite surveys"; and

(3) by adding after paragraph (2) the following new paragraphs:

"(3)(A) No decrease in the Federal medical assistance percentage of a State otherwise required to be imposed under paragraph (1) shall take effect—

"(i) before January 1, 1978;

"(ii) unless a notice of such decrease has been provided to the State at least 30 days before the date such decrease takes effect; and

"(iii) due to the State's unsatisfactory or invalid showing made with respect to a calendar quarter beginning after September 30, 1977, unless notice of such decrease has been provided to the State no later than the first day of the fourth calendar quarter following the calendar quarter with respect to which such showing was made.

"(B) The Secretary shall waive application of all or part (as is appropriate) of any decrease in the Federal medical assistance percentage of a State otherwise required to be imposed under paragraph (1) because a showing by the State, made under such paragraph with respect to a calendar quarter ending before October 1, 1977, is determined to be either unsatisfactory under such paragraph or invalid under paragraph (2), if the Secretary determines that the State's showing made under paragraph (1) with respect to the calendar quarter ending on December 31, 1977, is satisfactory under such paragraph and is valid under paragraph (2).

"(4)(A) The Secretary may not find the showing of a State, with respect to a calendar quarter under paragraph (1), to be satisfactory if the showing is submitted to the Secretary later than the 30th day after the last day of the calendar quarter, unless the State demonstrates to the satisfaction of the Secretary good cause for not meeting such deadline.

"(B) The Secretary shall find a showing of a State, with respect to a calendar quarter under paragraph (1), to be satisfactory under such paragraph with respect to the requirement that the State conduct annual onsite inspections in mental hospitals, skilled nursing facilities, and intermediate care facilities under paragraph (26) and (31) of section 1902(a), if the showing demonstrates that the State has conducted such an onsite inspection during the 12-month period ending on the last date of the calendar quarter—

"(i) in each of not less than 98 per centum of the number of such hospitals and facilities requiring such inspection, and

"(ii) in every such hospital or facility which has 200 or more beds,

and that, with respect to such hospitals and facilities not inspected within such period, the State has exercised

good faith and due diligence in attempting to conduct such inspections.

"(5) The Secretary shall submit to Congress, not later than 60 days after the end of each calendar quarter, a report on—

"(A) his determination as to whether or not each showing, made under paragraph (1) by a State with respect to the calendar quarter, has been found to be satisfactory under such paragraph;

"(B) his review (through onsite surveys and otherwise) under paragraph (2) of the validity of showings previously submitted by a State; and

"(C) any reduction in the Federal medical assistance percentage he has imposed on a State because of its submittal under paragraph (1) of an unsatisfactory or invalid showing.".

(b) The amendments made by subsection (a) shall become effective on June 30, 1977, and the Secretary of Health, Education, and Welfare shall promptly adjust payments made to States under section 1903 of the Social Security Act to reflect the changes made by such amendments.

I. Legislative Background

Legislation to amend the Social Security Act to strengthen the capability of the Government to detect, prosecute and punish fraudulent activities under the medicare and medicaid programs was introduced on January 4, 1977, by Mr. Rogers, Chairman of the Subcommittee and the Environment, and by Mr. Rostenkowski, Chairman of the Subcommittee on Health of the Ways and Means Committee. The bill was subsequently reintroduced as H.R. 3020, H.R. 3021, H.R. 3022, H.R. 3023, H.R. 4087, and H.R. 5702, with an additional 93 members of the House joining as co-sponsors, including 7 members of the Subcommittee on Health and the Environment. Joint hearings were held by the Health Subcommittees of the Interstate and Foreign Commerce Committee and the Ways and Means Committee on March 3 and 7. The bill was subsequently considered in open executive sessions by the Subcommittee on Health and the Environment, amended, and reported on April 28, 1977. The Subcommittee convened to reconsider the bill after the Ways and Means Committee had completed action, adopted additional amendments, and reported H.R. 3 with amendments on June 13, 1977. H.R. 3 was considered by the Interstate and Foreign Commerce Committee, and ordered reported by voice vote, on June 28, 1977.

The legislation reported by the Committee is a product of close consultation and cooperation throughout the stages of its development with the Committee on Ways and Means. In addition to holding joint hearings, the two Health Subcommittees held sequential executive sessions to consider the bill in the light of the actions taken by the other Committee members. As a result, both Committees are recommending very similar Committee amendments in reporting the bill to the House.

In order to minimize the differences in the amendments reported by each committee, the Committee on Interstate and Foreign Commerce

has included in its reported amendments some provisions which relate solely to part A of the medicare program (Hospital Insurance Benefits for the Aged and Disabled), which is in the jurisdiction of the Committee on Ways and Means. (Similarly, that committee has included in its reported amendments provisions relating solely to medicaid, which is the jurisdiction of the Interstate and Foreign Commerce Committee). It should be noted that substantive action on the amendments in these cases were carried out by the committee on jurisdiction. Adoption by the other committee was generally done pro forma. All provisions which were within both committees' jurisdiction, however, were fully considered by each.

II. Summary of the Bill

As reported, the provisions of H.R. 3, the Medicare-Medicaid Anti-Fraud and Abuse Amendments, are focused on six major areas: Strengthened program penalty sanctions, increased disclosure of information, needed improvements in the Professional Standards Review program, administrative reform, and other Medicaid amendments. The summary presented below briefly outlines the principal features of the bill as reported.

PROGRAM PENALTY SANCTIONS

1. The bill modifies the penalty provisions in existing law which relate to those persons providing services under medicare and medicaid. Most fraudulent acts now classified as misdemeanors are to become felonies. Penalties are to be increased to a maximum $25,000 fine, up to five years imprisonment, or both. The types of financial arrangements and conduct to be classified as illegal have been clarified. In addition, States will now be permitted to suspend the eligibility of medicaid recipients convicted of defrauding the program. However, the misdemeanor penalty presently provided under existing law for conviction of such individuals is retained, as is the misdemeanor penalty for the conviction of a beneficiary under the medicare program. The bill also requires the Health, Education, and Welfare Inspector General to include in his annual report an evaluation of the effort of the Department of Justice in the investigation and prosecution of fraud in the medicare and medicaid programs and his recommendations for improvement of that effort. (Section 4)

2. The bill requires the Secretary of Health, Education, and Welfare to suspend, for such period as he deems appropriate, from participation under medicare and medicaid, an individual practitioner who has been convicted of a criminal offense related to such individual's involvement in medicare or medicaid. When the Secretary suspends an individual, he must also notify the appropriate State licensing authorities, requesting that investigation be made and sanctions invoked in accordance with the State's law and public policy. (Section 7)

1. (a) The bill requires, as a condition of participation or certification in either medicare, medicaid or the maternal and child health program, the annual disclosure to the Secretary or the appropriate State agency by the participating entity of the identity of any person

who has a five percent or more ownership interest in the entity. These disclosure of ownership provisions will apply to medicare and medicaid providers of services (including independent clinical laboratories and renal disease facilities), entities furnishing services for which payment may be claimed under medicaid or the maternal and child health program (but not including any individual or group of practitioners), and medicare carriers or intermediaries and medicaid fiscal agents. Providers of services would also have to disclose similar ownership information about any subcontractor, five percent or more of which is owned by the provider. (Section 3)

(b) Furthermore, the bill modifies existing medicare and medicaid provisions relating to termination of medicare provider agreements or suspension of medicaid payments to health care entities by adding a requirement that a provider must comply with a request specifically addressed to it by the Secretary or the medicaid State agency for full and complete information as to any significant business transactions between it and any subcontractors or between it and wholly-owned suppliers. Finally, in the case of subcontractors having more than $25,000 in annual business transactions with a provider, compliance would be required with similar requests related to ownership information pertaining to the subcontractor. (Section 3)

2. The bill requires all institutional providers of services, or other agencies, institutions, or organizations, as a condition of participation or certification in medicare, medicaid or the social services programs under Title XX of the Social Security Act to disclose, in the application for participation or certification, the names of owners, officers, directors, agents, or managing employees who have been convicted of fraud against the medicare, medicaid, or State social service grant programs. Where an application contains the name of any such previously convicted individual, the Secretary or the State agency can refuse to enter into an agreement or refuse to contract with the applicant. The Inspector General of the Department of Health, Education, and Welfare must be informed of the receipt of any such applications and of any action taken on them. (Section 8)

3. The bill authorizes the Comptroller General of the United States to sign and issue subpenas in order to obtain necessary information and facilitate review of Social Security Act health programs. The Comptroller General will also be authorized, upon resistance or refusal by an individual to obey a subpena, to request a court order requiring compliance with the subpena. The bill would impose criminal sanctions for unauthorized disclosure by the GAO of individually identifiable personal medical records and would protect such records from subpena or discovery proceedings in connection with a civil suit. (Section 6)

4. The bill requires any provider of services participating in medicare to promptly notify the Secretary of its employment of an individual who, at any time during the preceding year, was employed in a managerial, accounting, auditing, or similar capacity by a medicare fiscal intermediary or carrier that services the provider. (Section 15)

5. The bill allows Federal access to the records of persons or institutions providing services under medicaid in the same manner that such access is presently provided to State agencies. (Section 9)

PROFESSIONAL STANDARDS REVIEW

The bill includes several provisions designed to clarify the nature and scope of PSRO review responsibilities, to enhance the capacity of PSRO's to perform reviews of the necessity and appropriateness of services more effectively, and to improve the administration and coordination of review activities so as to assure that program funds are properly expended. Thus, section 5 of the bill provides:

(1) for the termination of other duplicative review activities when the Secretary determines that a PSRO is competent to perform its review responsibilities; that the determinations of PSRO's so recognized by the Secretary with respect to the necessity and appropriateness of care are conclusive for purposes of program payment; and that the role of the State in the process of establishing and evaluating PSRO review of services provided through the medicaid program will be increased and made more specific;

(2) that a PSRO may be conditionally designated for a period not to exceed 48 months (with authority for the Secretary to extend the period for an additional 24 months where warranted by unusual circumstances); and that PSRO's must assume review responsibilities for institutional services during this period;

(3) for the Secretary to develop ambulatory care review methodologies for use by PSRO's and to make such methodologies available within 2 years; to require a PSRO, where he finds it is capable of undertaking ambulatory care review, to undertake such review no later than 2 years after it becomes fully operational; and to give priority to requests by PSRO's to review services in "shared health facilities";

(4) that the Federal Government may assume the defense costs incurred by a PSRO in a liability suit related to the performance of its functions;

(5) for the disclosure of information with respect to evidence of fraud to designated Federal and State law enforcement agencies (with a prohibition against access to PSRO records in the case of subpena or discovery proceedings in a civil action), and for the disclosure of aggregate statistical data to Federal and State health planning agencies;

(6) for the annual submission to the Congress by the Secretary of a comprehensive report on the administration, cost, and impact of the PSRO program;

(7) for a prohibition against any PSRO disclosing to a Federal official, or a Federal official having access to, any individually identifiable medical record in the possession of a PSRO relating to medical care not provided or paid for by the Federal Government without the specific consent of the patient. The Department of HEW would also be required to submit its legislative recommendations to the Congress as to the appropriate procedure for maintaining the confidentiality of individual medical records. These recommendations would be made after taking into consideration the final report of the Privacy Protection Study Commission and must be submitted to the Congress no later than 90 days after the Privacy Commission's report is issued; and

(8) for several clarifying administrative and technical changes designed to enhance a PSRO's operational capacity. (Section 5)

ADMINISTRATIVE REFORM

1. The bill authorizes the Secretary to assign and reassign providers to available intermediaries, after taking into account any preferences expressed by the providers and after applying objective performance standards to the original nominee of the provider prior to making a reassignment. Any assignment action he takes must be based on a finding that it will result in more efficient and effective administration of the program. Before making any assignment or reassignment that is not in accord with the provider's choice, the Secretary must furnish to the provider and its chosen intermediary a full explanation of his findings with respect to efficiency and effectiveness and provide an appropriate opportunity for a hearing, which is subject to judicial review.

The Secretary is also authorized to designate regional intermediaries or a national intermediary with respect to a class of providers (e.g., home health agencies) where he determines that, after applying objective performance standards to agencies or organizations that would be adversely affected, such designation will result in more efficient and effective administration of the program. In a similar manner to that mentioned above, this authority to designate with respect to a class of providers is subject to a requirement that the Secretary fully explain to the affected parties his findings with respect to efficiency and effectiveness and provide an appropriate opportunity for a hearing which is subject to judicial review. (Section 14)

2. The bill requires the Secretary to establish for each of the different types of health services institutions a uniform system for the reporting of such items as cost of operation, volume of services, rates, capital assets and bill data. This reporting system would be mandated for use by medicare and medicaid providers and such use would be phased in by type of provider. (Section 19)

3. The bill repeals the program review team provisions of present law. The functions formerly performed by such teams with respect to the quality and utilization of services will be performed by Professional Standards Review Organizations. (Section 13)

4. The bill would encourage each State to establish an office separate from the medicaid program agency to prepare and prosecute cases of suspected fraud and abuse in the program by providing for 90 percent Federal matching funds for expenditures to establish and operate State medicaid fraud control units. (Section 17)

5. The bill also requires States to make provision in their State medicaid plan for claims payment procedures which ensure that 90 percent of the bills submitted by eligible noninstitutionally-based providers will be reimbursed within 30 days, and 99 percent within 60 days. The State would not be cited for noncompliance if the Secretary found the State was acting in good faith to achieve this goal. (Section 2)

6. The bill directs the Comptroller General to conduct a comprehensive review of the administrative structure for the processing of medicare claims. (Section 12)

7. The bill requires the Secretary of Health, Education, and Welfare to report to the Congress within 12 months after enactment of this legislation with an analysis and recommendations relating to all aspects (including the availability, administration, provision, reimbursement procedures and cost) of the delivery of home health services under medicare, medicaid and the title XX social services program. (Section 18)

TECHNICAL REVISION

1. Your committee's bill clarifies existing law to insure that a power of attorney cannot be used to circumvent the prohibition in existing law against the use of "factoring" arrangements in connection with the payment of provider claims by the medicare and medicaid programs. (Section 2)

2. The bill modifies the provisions of existing law related to the rental or purchase of durable medical equipment to mandate that the Secretary require the purchase of such equipment where purchase will be less costly than extended rental payments. (Section 16)

3. The bill increases individual state's incentives to adopt a computerized medicaid claims processing and information retrieval system by modifying one current requirement for higher Federal matching funds for the development and operation of this system. The bill would require such systems to provide explanation of benefits information to only a sample group of medicaid recipients rather than to each recipient as is currently required. (Section 10)

4. The bill would preclude Federal matching of State medicaid expenditures that result from State laws or contracts which exclude or limit insurance benefits because an individual is eligible for medicaid. (Section 11)

OTHER MEDICAID AMENDMENTS

The bill provides an additional six-month period to States to meet the requirements of the current law concerning review of care delivered in long-term care institutions. The section provides that if a State is in compliance for the year period ending December 31, 1977, the Secretary shall waive all (or such part as is appropriate) of the reduction which would otherwise be imposed on those States that failed to fulfill the requirements of the law during previous periods. Further the section specifies: 1) that the Secretary must provide States with a 30-day notice before reducing funds, 2) that the Secretary must complete his validation surveys of State reviews and give notice of any reduction resulting from his findings within 9 months of the close of the year in question, and 3) that good faith attempts to perform reviews of all institutions, and actual review of all large institutions and 98 percent of all other institutions, will be considered full compliance with the requirements of the law. (Section 20)

III. Cost of Legislation

As reported by the Committee, H.R. 3 as amended provides authorization for an increase in the Federal matching rate for the Medicaid program as follows:

(a) It provides 90 percent Federal matching for State expenditures to support programs of educational and technical assistance to expedite

the filing and payment of claims. The higher Federal matching is authorized for a 3-year period only. A maximum of $5 million in aggregate expenditures annually is placed on funds available at the higher matching rate.

(b) It provides 90 percent Federal matching for expenditures to establish and operate State Medicaid fraud control units which meet certain specified standards. The higher Federal matching is authorized for a 3-year period only. A maximum on the annual amount any State could receive at the higher matching rate is established at one-quarter of 1 percent of Medicaid expenditures in the State, or $500,000, whichever is greater.

The bill also delays reductions of Medicaid matching funds imposed on the States because of failure to meet the requirements of the law for review in long-term care institutions. The reduction is waived if a State comes into compliance with the requirements of the law by December 31, 1977.

However, because the provisions of the law are designed to increase program efficiency and ability to detect and prosecute fraud, reductions in program expenditures resulting from H.R. 3 are expected to offset any increase in expenditures resulting from the provisions of the bill. As set forth in the Congressional Budget Office estimate which appears later in this report, no increase in cost is estimated to occur.

IV. Purpose and Background of the Bill

In recent years, numerous hearings, studies, and investigations undertaken by this committee and other committees of the Congress, the General Accounting Office, and other Federal and State agencies have demonstrated that there exist, to a disturbing degree, fraudulent and abusive practices associated with the provision of health services financed by the medicare and medicaid programs. The disclosures to date have focused on a broad range of improper activities which are not restricted to one particular class of providers or treatment settings. In whatever form it is found, however, fraud in these health care financing programs adversely impacts on all Americans. It cheats taxpayers who must ultimately bear the financial burden of misuse of funds in any government-sponsored program. It diverts from those most in need, the nation's elderly and poor, scarce program dollars that were intended to provide vitally needed quality health services. The wasting of program funds through fraud also further erodes the financial stability of those state and local governments whose budgets are already overextended and who must commit an ever-increasing portion of their financial resources to fulfill the obligations of their medical assistance programs. In addition to these adverse financial consequences, the activities of those who seek to defraud these programs unfairly call into question and honesty and integrity of the vast majority of practitioners and health care institutions.

Fraud and abuse can occur in a number of different medical settings. Recent investigations have demonstrated the pervasiveness of the problem.

A. SHARED HEALTH FACILITIES

Many of the more flagrant examples of fraud and abuse activities have been uncovered in so-called "shared health facilities," also referred to as medicaid "mills." Typically, these are unregulated, unlicensed, and poorly equipped storefront units located in ghetto areas of large metropolitan cities. Such mills derive their primary business from welfare patients.

Owners of these facilities are usually individuals who have joined together in a partnership or corporation arrangement. Some may own more than one facility. Some may also be providers on the facility premises or at another location. They may also own pharmacies or laboratories which are often used as the exclusive lab or pharmacy service by all practitioners in the facilities. In certain instances there is overlapping ownership between medicaid mills and factoring companies.

Many medicaid practitioners in urban areas, with little working capital and often holding foreign medical degrees, turn to medicaid mills. These are usually owned by real estate operators who have sufficient capital to purchase the land, office space, and equipment necessary to operate a medical practice. In turn, the average practitioner will pay from 30 to 40 percent of gross income as rent, will lose 12 percent of his income to the factoring agency, and in a large number of cases be asked to divide the remaining net 50–50 with the mill owner. In some mills, the practitioners' total medicaid income is turned over to the mill operator and the practitioner receives a commission based on dollar volume (an average of 20 to 40 percent to the practitioner and 60 to 80 percent to the mill operator).

The most common violations in the mills include:

(1) "ping-ponging"—referring of patients from one practioner to another within the facility even though there is no medical reason for doing so;

(2) "ganging"—billing for multiple services to realtives who accompany a family member who alone had sought treatment at the mill;

(3) "upgrading"—billing for a service more extensive than that actually provided;

(4) "steering"—directing a patient to a particular pharmacy, a violation of the medicaid program's policy of freedom of choice; and

(5) billing for services not rendered—either adding services not performed onto an invoice carrying legitimate billings or submitting a totally fraudulent claim.

Other violations include soliciting offering, or receiving kickbacks; billing twice or more for the same service; and billing both medicare and medicaid for the same service.

Fee splitting and percentage lease arrangements are common practices and often go hand-in-hand with medicaid mills. Percentage lease arrangements are a basic economic incentive to form these facilities. Percentage lease arrangements give the landlord a percentage of the provider's gross income in return for office, space, equipment, shared waiting rooms, laboratory services, custodial and office help, and often administrative services. Studies have shown that the average per-

centage lease in New York City, for example, appeared to range from 30 to 40 percent of the providers' gross fees for most medical disciplines. While the American Medical Association has ruled this practice unethical, it is not considered illegal in most States and is not prohibited under Federal law or regulations.

Factoring is also a very common practice associated with medicaid mills. Although factoring was outlawed under the Social Security Amendments of 1972, factoring firms have evaded statutory intent by working under a power of attorney arrangement.

B. CLINICAL LABORATORIES

Both medicare and medicaid provide coverage for laboratory services provided by independent clinical laboratories. Over the past several years, there has been increasing concern over the potential for fraud and abuse among clinical laboratories, particularly for services funded by the medicaid program. Several State commissions and legislative investigative committees have focused attention on this issue. At the Federal level, two congressional committees and the General Accounting Office have also examined service and billing patterns in these facilities.

The House Committee on Interstate and Foreign Commerce reviewed the question of fraud and abuse in clinical laboratories within the context of overall improvements needed in such facilities. Testimony presented to the committee by the executive director of the New Jersey State Commission of Investigation indicated that physicians often determined which laboratories would do the test work for their medicaid patients by the amount of the kickbacks and rebates offered by the laboratory. Testimony before the committee's Subcommittee on Oversight and Investigations indicated that these kickbacks are in the neighborhood of 25 percent.

Kickbacks take a number of forms including cash, long-term credit arrangements, gifts, supplies and equipment, and the furnishing of business machines. The most common practice, however, involves the "rental" of small office space in a medical clinic for amounts which are far in excess of the reasonable value of the space. Frequently, the "rent" is determined by paying a percentage of the business sent to the laboratory, often in amounts as high as 30 to 45 percent of the medicaid billings of the physician or clinic sent to the laboratory.

C. NURSING HOMES

Nursing home fraud and abuse has also been the subject of extensive study and investigation. Numerous reports and hearings have been published by congressional committees, Federal agencies, and State commissions which document such activities as patient abuse, substandard homes, deceptive real estate practices, false cost reporting, and kickback practices.

Fraudulent and abusive practices relating to program costs involve the intentional misrepresentation or falsification of the costs involved in providing patient care. These practices may take many forms. Examples include: deceptive real estate practices which artificially inflate property costs, false or misleading cost reports which hide non-

allowable costs, inadequate accounting procedures which prohibit effective auditing, kickbacks from vendors, and failure to disclose ownership interests. Among other questionable activities engaged in by some nursing home owners and operators are:

(1) *Deceptive non-arms-length transactions.*—Increased medicaid reimbursement can result from failure to disclose a "non-arms-length transaction" for services, realty or goods provided to the nursing home. This type of transaction is defined as an arrangement in which the nursing home operator has at least a 10 percent interest in the equity of a company providing real property, goods, or services to the facility.

(2) *Reporting other business expenses on the nursing home's books.*—Some nursing home owners attempt to put the expense of other business interests on the nursing home's records. These include real estate taxes, maintenance supplies, and insurance and fuel expenses.

(3) *Unauditable books.*—The books of some nursing homes are practically unauditable. A case was reported where an owner kept one set of books for three of his homes with records so jumbled that according to the State auditor "they defied all ordinary auditing procedures."

D. INDEPENDENT PRACTITIONERS

An independent practitioner's income from medicaid and medicare is based in part on the volume and complexity of the services he provides. Thus, for the practitioner, program fraud and abuse covers a broad spectrum of practices, ranging from the rendering of services of arguable medical necessity to such criminal offenses as filing false claims.

There is much less evidence of fraud and abuse among practitioners than by nursing homes, medicaid mills, and independent laboratories. However, there is no way to estimate the extent to which fraud and abuse by practitioners has gone undetected. Much of the evidence that has been collected in these other areas has been based on the testimony of associates, a review of business records, and other investigative techniques that are impractical or less suitable for the review of an individual practitioner's activities. Detection and proof of fraud or abuse by an individual practitioner must often depend on the patient, who may well be both old and sick, and without medical knowledge. In any case, whatever its true extent might be, it is clear that the potential for exploitation exists for those practitioners that choose to cheat medicaid and medicare.

Perhaps the most flagrant fraud involves billings for patients whom the practitioner has not treated. A related form of fraud involves claims for services to a practitioner's patients that were not actually furnished and intentionally billing more than once for the same service.

Furnishing excessive services is probably the most costly noncriminal abuse faced by health benefit programs. At the same time, it is relatively difficult to prove and correct. Since the medical needs of a particular patient can be highly judgmental, it is difficult to identify program abuse as a practical manner unless the overutilization is grossly unreasonable.

H.R. 3 is designed to strengthen the ability of the Federal and State governments to find and correct abuse and to detect and prosecute fraud. Fraud involves an intentional deception or misrepresentation, with the intent of receiving some unauthorized benefit for the individual engaged in fraud. In the health area, examples of fraud may include: billing for services not rendered, misrepresentation of services rendered, kickbacks, deliberate duplicate billing, false or misleading entries on cost reports, and so forth. Program abuse is less clearly defined and includes activity wherein providers, practitioners, and suppliers of services operate in a manner inconsistent with accepted, sound medical or business practices resulting in excessive and unreasonable financial cost to either medicare or medicaid. Included in the area of abuse are the provision of unnecessary health services and the provision of necessary care in unnecessarily costly settings.

To deal with the problem of fraud, more effective prosecution efforts and stiffer criminal penalties are proposed. Additionally, since issues of medical necessity and quality of care may be present in cases of possible program abuse (as distinct from criminal fraud), PSRO's can be a valuable resource for the exercise of the professional medical judgment that may need to be made in certain of such cases. The committee believes that every effort must be made to encourage the rapid implementation of the PSRO program. To achieve this end, H.R. 3 includes several provisions making modifications in the administrative structure of the program to enhance the capacity of individual PSRO's to effectively review matters of quality and necessity.

V. Committee Proposal

Explanation, justification, and comparison with present law

Prohibition Against Assignment by Physicians and Others of Claims for Services; Claims Payment Procedures for Medicaid Program (Section 2)

The Committee's bill would modify existing law to preclude the use of a power of attorney as a device to circumvent the existing ban on the use of "factoring" arrangements in connection with the payment of claims by the medicare and medicaid programs. The bill further requires State medicaid programs to provide for timely claims payment procedures and provides higher Federal matching funds for a three-year period to assist States with programs of educational and technical assistance to expedite the filing and payment of claims.

In 1972, the Congress took action to stop a practice under which some physicians and other persons providing services under medicare and medicaid reassigned their medicare and medicaid receivables to other organizations or groups. Under the conditions of these reassignments, the organizations or groups purchased the receivables for a percentage of their face value, submitted claims and received payments in their name. By 1972, it had become apparent that such reassignments were a significant source of incorrect and inflated claims for services paid by medicare and medicaid. In addition, cases of fraudulent billings by collection agencies and substantial overpayments to these so-called "factoring" agencies were also found.

Congress concluded that such arrangements were not in the best interest of the government or the beneficiaries served by the medicare and medicaid programs. The Social Security Amendments of 1972, Public Law 92–603, therefore, included a prohibition against the payment for covered services to anyone other than the patient, his physician, or other person who provided the service, unless the physician or other person is required as a condition of his employment to turn his fees over to his employer, or unless the physician or other person has an arrangement with a facility under which the facility bills for such services.

Despite these efforts to stop factoring of medicare and medicaid bills, some practitioners and other persons have circumvented the intent of the law by use of a power of attorney. The use of a power of attorney allows the factoring company to receive the medicare or medicaid payment in the name of the physician, thus allowing the continuation of program abuses which factoring activities were shown to produce in the past.

The bill would modify existing law to preclude the use of a power of attorney as a device for reassignments of benefits under medicare and medicaid, other than an assignment to a governmental entity or establishment, or an assignment established by or pursuant to the order of a court of competent jurisdiction. The bill also provides for similar prohibitions with respect to billings for care provided by institutions under medicare and medicaid. However, it would not preclude the agent of a physician or other person furnishing services from collecting any medicare or medicaid payment on behalf of a physician, provided the agency does so pursuant to an agreement under which the compensation paid the agency for his services or for the billings or collections of payments is unrelated (directly or indirectly) to the dollar amount of the billings or payments, and is not dependent upon the actual collection of any such payments. Thus, the use of billing agents by doctors and others, when the agents are paid on a basis related to the cost of doing business and not dollar amounts billed or collected, would not be precluded. The bill would not impose any limitations on the use of billing or collection agencies for payments owed by anyone other than the medicare or medicaid programs. Nor is it the committee's intention that this provision preclude the legitimate transfer of accounts receivable from these programs by an individual or an institution upon the "sale" of the individual's practice (for example upon retirement) or as part of the sale of all the assets of an institution.

The committee received considerable testimony indicating that undue delay in medicaid claims payments contributes to the rise of factoring arrangements as well as discourages physicians from participating in the program. The committee wishes to assure that the ban on factoring arrangements will not impose an undue hardship on medicaid practitioners. The bill therefore requires State medicaid plans to provide for claims payment procedures which ensure that 90 percent of claims for services furnished by health care practitioners through individual or group practices or through shared health facilities are paid within 30 days of receipt; 99 percent of such claims must be paid within 60 days of receipt. State plans must further provide for procedures for prepayment and postpayment claims review. The bill permits the Secretary of Health, Education, and Welfare to waive this

State plan requirement if he finds that a State has exercised good faith in trying to ensure timeliness and accuracy in its claims payment operation. Among other things the Secretary should take into account in making a waiver determination is whether the State has received an unusually high volume of claims which are not clean claims (i.e., claims for which no further written information or substantiation is required from the provider).

In many areas of the country, a significant volume of medicaid claims submitted are inadequately or incorrectly filed. The bill therefore authorizes 90 percent Federal matching from January 1978 through September 1980 for the costs attributable to the conduct of such educational and technical assistance programs for health care practitioners as the Secretary determines are likely to expedite the filing and payment of claims. Technical assistance may be provided through such means, including outreach offices, the media, and telephone systems, as the Secretary determines to be appropriate. The maximum amount of payment available to the States under this section may not exceed $1.25 million in any calendar quarter. If the aggregate amount of payment would otherwise exceed this limitation, the amount made available to each State would be proportionately reduced.

Disclosure of Ownership and Financial Information (Section 3)

The Committee's bill would require entities (other than individual practitioners or groups of practitioners) providing services under medicare, medicaid, or the maternal and child health program to disclose certain ownership interests, as a condition of program participation. These discolsure requirements would also be applied to medicare intermediaries and carriers and medicaid fiscal agents. Disclosure of additional ownership and financial information would be required, but only when specifically requested.

Current law and program policies already require the provision of certain ownership and financial information pertaining to entities providing services under medicare and medicaid. For example, an agreement with a provider of services under medicare may be terminated if the provider fails to furnish information necessary to validate the amount of payment claimed. In a different context, present law requires, as a medicare and medicaid condition of participation, a skilled nursing facility to disclose to the Secretary or appropriate State agency, and keep current, the name of anyone having significant ownership interest in the facility. Intermediate care facilities under medicaid are also required to disclose information on significant ownership interests.

The Committee believes, however, that the information required under current law is often insufficient to facilitate the detection of fraudulent practices. Information now required does not provide adequate documentation on persons with significant ownership interests in more than one facility or other entity participating in medicare, medicaid, or the maternal and child health program. Information is not specifically required to identify persons with significant ownership interests in related companies that supply goods and services to providers or other participating entities. Authority to obtain information on financial transactions with related suppliers or with subcontractors is not clearly defined in law.

To remedy these problems, the bill would require disclosure of specified ownership information to the Secretary or the appropriate State agency, as a condition of an entity's participation, certification, or recertification under medicare, medicaid, or the maternal and child health program. Entities required to disclose would be defined as: Medicare providers of services (as defined in section 1861(u), which includes hospitals, skilled nursing facilities, and home health agencies), independent clinical laboratories, renal disease facilities, and all entities (other than individual practitioners or groups of practitioners) that claim reimbursement for services provided under medicaid or the maternal and child health program. In addition, the bill would require medicare intermediaries and carriers and medicaid fiscal agents to disclose specified ownership information as a condition of contract or agreement approval or renewal under titles XVIII and XIX.

The bill specifies that disclosing entities must supply full and complete information as to the identity of each person who:

(1) has a direct or indirect ownership interest of five percent or more in the entity,

(2) owns (in whole or part) a five percent interest in any mortgage secured by the entity,

(3) is an officer or director of the entity, if it is organized as a corporation, and

(4) is a partner in the entity, if it is organized as a partnership.

Where disclosing entities providing services under medicare or medicaid own five percent or more of a subcontractor, similar ownership information would be required to be disclosed about the subcontractor.

In addition, the bill would require, to the extent feasible, that information about a person's ownership disclosed by an entity must also include information with respect to ownership interest of that person in any other entity which is required to comply with disclosure requirements under the bill.

The bill would also modify the existing provisions of title XVIII and XIX which relate to termination of medicare provider agreements or suspension of medicaid payments to health care entities (other than individual practitioners and groups of individual practitioners) by adding two additional requirements. The bill would require a provider entity to comply with specific requests addressed to it by the Secretary or the State medicaid agency for full and complete information on: (1) the ownership of any subcontractor (as defined in regulations) with whom the provider has annual business transactions of more than $25,000, and (2) any significant business transactions (as defined in regulations) between it and any subcontractor or between it and any wholly-owned supplier.

In developing regulations to define subcontractors and suppliers, the Committee intends that a distinction be made between agencies and organizations from which a provider only purchases goods and services to assist it in meeting its obligations to patients and those agencies and organizations to which a provider has actually delegated some of the duties and obligations it has directly to its patients. Although the facts and circumstances of individual situations may differ, it is contemplated under such a delineation that the relationship between

a hospital and a commercial laundry would be considered to be that of a provider and its supplier, but that the relationship between a hospital and a management company with which it has contracted to administer either all or part of the day-to-day operations of the institution or the relationship between a hospital and an independent radiological service would be that of a provider and a subcontractor.

The bill specifies that the Secretary is to determine by regulation the meaning of the phrase "directly or indirectly" with respect to persons having ownership interests in disclosing entities. In directing him to do this, the Committee is acutely aware of the difficulties involved in developing this definition, particularly when the phrase "persons with ownership interests" is interpreted to mean a corporation. Institutional providers of health care often are owned by corporate entities which in turn are owned by other corporations. In order to compile accurate information on persons with ownership interests in disclosing entities, the Committee believes it is also necessary to obtain information on persons with ownership interests in these other corporations. The information to be disclosed under the bill must go beyond the listing of corporate identities unless that corporation is already subject to ownership disclosure under the statutes administered by the Securities and Exchange Commission or other Federal regulatory agencies. It is intended, at the minimum, to identify those persons with ownership interests of five percent or more in a nonpublicly held corporation that owns a disclosing entity. In addition, the Secretary may determine that it is necessary to require disclosure of persons with ownership interests in nonpublicly held corporations beyond the first level of corporate ownership where the concept of "pyramiding" of corporate structures appears to be present.

The committee views the disclosure requirements imposed by the bill to be of critical importance in the process of detecting and deterring fraudulent and abusive practices within the medicare, medicaid, and the maternal and child health programs. The Committee does not intend, however, or these requirements to be unduly burdensome on providers and other entities to which they apply. The provisions were designed to be incorporated into the ongoing certification or contractual process. It is, therefore, expected that their implementation and administration will be accomplished in such a way as to preclude unnecessary additional administrative burdens on those complying with them.

Penalties for Defrauding Medicare and Medicaid (Section 4)

The committee bill would modify the penalty provisions in existing law which relate to those persons providing services under medicare and medicaid.

Existing law provides specific penalties under the medicare and medicaid programs for certain practices that have long been regarded by professional organizations as unethical, which are unlawful in some jurisdictions, and which contribute significantly to the cost of the programs. Such practices as the submission of false claims, or the soliciting, offering, or acceptance of kickbacks or bribes, including rebates or a portion of fees or charges for patient referrals, are misdemeanors under present law and punishable by a maximum $10,000 fine, up to one year imprisonment, or both. In addition, the making of false state-

ments with respect to material facts concerning the conditions of health care facilities in order to qualify for certification under medicare and medicaid is considered a misdemeanor and punishable by a maximum $2,000 fine, up to six months in prison, or both.

Recent hearings and reports, however, indicate that such penalties have not proved adequate deterrents against illegal practices by some individuals who provide services under medicare and medicaid. In addition, these misdemeanor penalties appear inconsistent with existing Federal criminal code sanctions which make similar actions punishable as felonies. Also, it has been brought to the attention of the committee by U.S. Attorneys' offices which have utilized these Social Security Act sanctions in the prosecution of medicare and medicaid fraud cases that the existing language of these penalty statutes is unclear and needs clarification.

The bill would strengthen the penalty provisions in existing law which relate to persons providing services under medicare and medicaid. Most fraudulent acts now classified as misdemeanors would become felonies. Penalties for these acts would be increased to a maximum $25,000 fine, up to five years imprisonment or both.

In addition, the bill would clarify and restructure those provisions in existing law which define the types of financial arrangements and conduct to be classified as illegal under medicare and medicaid.

It would make subject to the penalty provisions any person who solicits or receives any remuneration (1) in return for referring an individual to a person for the furnishing, or arranging for the furnishing of items or services; or (2) in return for purchasing, leasing, or ordering, or arranging for, or recommending the purchasing, leasing, or ordering of goods, facilities, or services. Also, any person who offers or pays any remuneration to any person to induce such person to do similar activities would be subject to the penalty provisions.

The bill would define the term "any remuneration" broadly to encompass kickbacks, bribes, or rebates which may be made directly or indirectly, overtly or covertly, in cash or in kind (but would exclude any amount paid by an employer to an employee for employment in the provision of covered items or services).

The bill would specifically exclude the practice of discounting or other reductions in price from the range of financial transactions to be considered illegal under medicare and medicaid, but only if such discounts are properly disclosed and reflected in the cost for which reimbursement could be claimed. The committee included this provision to ensure that the practice of discounting the normal course of business transactions would not be deemed illegal. In fact, the committee would encourage providers to seek discounts as a good business practice which results in savings to medicare and medicaid program costs.

In addition, the committee bill would allow States to suspend, for a period not to exceed one year, the eligibility of medicaid recipients convicted of defrauding the program. However, the misdemeanor penalty provision presently provided under existing law for conviction of such individuals would be retained (maximum fine of $10,000, up to one year imprisonment, or both) as would be the penalty for conviction of a beneficiary under the medicare program.

In its consideration of this bill, the committee has focused considerable attention on the activities of the Department of Justice to investigate and prosecute fraud in the medicare and medicaid programs. The committee believes that the Department must develop the resources to combat this complex type of criminal activity. The Attorney General has made a commitment to strengthen departmental efforts in this area and intends to monitor those efforts quite closely. The letter of the Attorney General to the Chairman of the Health Subcommittee of the Ways and Means Committee outlining departmental initiatives in this area follows:

OFFICE OF THE ATTORNEY GENERAL.
Washington, D.C., May 12, 1977.

Hon. DAN ROSTENKOWSKI,
Chairman, Subcommittee on Health, Committee on Ways and Means, House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: I am writing you again with refernce to the proposal to include in H.R. 3 a mandate for the establishment of a separate and identifiable organizational unit within the Department's Criminal Division to carry out specified functions relating to investigation and prosecution of criminal violations in the programs of health insurance and medical assistance provided under the Social Security Act. As I indicated in my appearance before your Subcommittee, I fully concur in the need for vigorous investigation and prosecutions of fradulent activities in the medicare-medicaid program. I strongly feel, however, that the aforementioned provision is unnecessary and would set an undesirable precedent by dictating in law a particular subordinate organization within the Criminal Division.

In recognition of the importance of taking effective action against medicare-medicaid abuses, we are currently taking the following steps.

1. We have within the Fraud Section of the Criminal Division a program fraud unit which coordinates Department efforts directed against program abuse and maintains regular liaison with program agencies including HEW.

2. We are currently working on preparation of a Medicaid Enforcement Manual for distribution to Assistant United States Attorneys to assist them in prosecuting medicaid-medicare cases.

3. We are meeting on a regular basis with the Inspector General and his staff of HEW in an attempt to develop strategies and enforcement priorities within medicaid-medicare areas.

4. There is a separate program fraud unit within the Public Integrity Section which focuses on situations involving corruption of government officials in the administration of programs.

5. We are attempting to identify significant cases in order to insure that ample resources are devoted to their development and prosecution.

6. Many of the larger of the United States Attorneys offices, including the Southern District of New York and Chicago, have established separate program fraud units within the district to focus on these types of offenses.

I have every intention of continuing emphasis in this area. I do respectfully recommend, however, against placing in the law the requirement of a specific organization entity for this purpose. I am afraid that other Congressional committees will feel that they must support

similar organizational requirements in law for their programs to insure that such programs receive appropriate attention. A proliferation of special units would inevitably lead to confusion, lack of flexibility and be self-defeating of the purposes intended.

Sincerely,

GRIFFIN B. BELL, *Attorney General.*

In addition the bill modifies section 204(a) of Public Law 94–505, relating to the annual reports of the Health, Education and Welfare Inspector General, to require the Inspector General's report to include an evaluation of the performance of the Attorney General in the investigation and prosecuting of criminal violations relating to fraud in the medicare and medicaid programs and include any recommendations with respect to improving the performance of such activities.

Amendments Related to Professional Standards Review Organizations (Section 5)

Waiver of Other Review Requirements (Section 5(a))

The committee's bill provides that where the Secretary finds a given Professional Standards Review Organization (PSRO) competent to perform required review functions, similar activities otherwise required by law would not apply, except to the extent specified by the Secretary.

Under present law, the Secretary is authorized to waive any or all of the review, certification, or similar activities otherwise required under the law where he finds, on the basis of substantial evidence of the effective performance of review and control activities by PSRO's, that the activity or activities are no longer needed for the provision of adequate review and control. The purpose of this provision was to avoid duplication of review functions. Current law does not specifically state that the waiver authority is applicable to conditionally designated organizations, although the language has been interpreted to permit such actions.

The bill would both clarify present law and simplify its application by providing that where the Secretary makes a formal determination that a given PSRO is competent to perform required review functions, the review, certification and similar activities otherwise required by law would not be applicable with respect to those providers, suppliers, and practitioners being reviewed by such PSRO, except to the extent specified by the Secretary. A finding by the Secretary under this subsection could be made both with respect to conditionally designated and qualified PSRO's. The provision would not affect other provisions of existing law relating to determinations with respect to conditions for eligibility to or payment of benefits (as distinct from reviews or certifications of medical necessity).

Modification of Requirements for Conditionally Designated PSRO's (Section 5(b))

The committee's bill extends the time period for conditional designation of PSRO's and clarifies the language of present law pertaining to the duties and functions a PSRO must assume during this trial period.

Current law provides that each PSRO shall initially be designated on a trial basis for a period not to exceed two years. By the end of the

period, the organization shall be considered a qualified organization only if the Secretary finds that it is substantially carrying out in a satisfactory manner the functions required of a PSRO with respect to institutional services in its area. When the legislation was enacted, it was anticipated that conditionally designated organizations would be able to assume review responsibilities with respect to all institutional services within a two-year period. Implementation of the program has been slower than anticipated with the major focus to date on review of inpatient hospital services. A number of conditionally designated organizations have or are approaching the end of their two-year trial period. While many are effectively performing reviews of services, they are technically not eligible for continuation of their conditional status or designation as qualified organizations.

The bill modifies the conditional designation provision of present law to provide for a conditional period not to exceed 48 months. The Secretary would be authorized to extend this period for an additional 24 months if an organization has, for reasons beyond its control, been unable to satisfactorily perform all of its required functions. The committee expects that this extension of the conditional period would be authorized only in unusual circumstances.

The bill also clarifies the requirement of present law that PSRO's must assume responsibility for review of all institutional services (including ancillary services) during the conditional period. Additionally, the bill clarifies the requirement that PSRO's must be reviewing long-term institutional care services (subject to the provisions of section 5(d) which leave the responsibility for review of services in intermediate care facilities with the State medicaid agency unless the Secretary finds the State is not performing effective review).

Review Requirements (Section 5(c))

The committee's bill requires the Secretary to give priority to PSRO requests to review services provided in "shared health facilities"; mandates the development of ambulatory care review methodologies for use by PSRO's; requires a PSRO to undertake ambulatory care review not later than two years after it has achieved operational status; and modifies the language in current law pertaining to physicians excluded from participation in review activities.

Under current law, a PSRO is required to review only care provided by or in institutions. It may request authority to review other kinds of health services, and the Secretary may approve the request at his option. To date, little emphasis has been given to the assumption of review responsibility by PSRO's for other kinds of health care services.

The bill would require the Secretary to give priority to requests by PSRO's to review services in "shared health facilities" with the highest priority being assigned to requests from PSRO's located in areas with substantial numbers of such facilities. A "shared health facility" is defined as an arrangement meeting all of the following criteria:

(1) Two or more practitioners practice their professions at a common physical location;

(2) The practitioners share common space, services of supporting staff or equipment;

(3) The practitioners have a person (who may himself be a practitioner), paid on a percentage or other basis clearly unrelated

to the value of the services provided, who either is in charge of or supervises substantial aspects of the operation or who makes available services of supporting staff who are not employees of such practitioners; and

(4) At least one of the practitioners receives from medicare, medicaid, and maternal and child health fee-for-service payments in excess of $5,000 for one month or $40,000 for 12 months.

The term "shared health facility" specifically excludes hospitals, skilled nursing facilities, home health agencies, federally approved health maintenance organizations, hospital cooperative shared services organizations meeting the requirements of section 501(e) of the Internal Revenue Code, or any public entities.

The definition of a "shared health facility" is designed to distinguish those types of ambulatory facilities (sometimes referred to as "Medicaid Mills") which are characterized by a high volume of services to medicaid patients (often of an excessive or unnecessary nature), and the payment of a percentage of the medicare and medicaid billings to the owner or manager of the facility, from legitimate group practice arrangements under which several practitioners render services at a common location. Since a shared health facility could evade the test of percentage arrangements, the Secretary has leeway to determine whether the payments to the owner or manager, while technically not a percentage of billings, are clearly unrelated to the value of the services provided by such person to the facility. By requiring a facility to meet all four criteria specified in the bill, it is expected that such legitimate arrangements among practitioners would be excluded from the definition. The Committee expects, therefore, that the Department will exercise judgment in applying this definition so as to assure that legitimate group practice arrangements are not inappropriately classified.

Recent congressional hearings and reports have documented widespread instances of fraud and abuse in certain types of ambulatory facilities which have come to be known as "Medicaid Mills." The definition of shared health facilities is designed to identify these specific types of arrangements in order to facilitate PSRO review of the services furnished by such facilities. Committee wishes to emphasize that a PSRO is not a fraud detection organization; its role is to render professional determinations as to the medical necessity and appropriateness of services. Thus, a PSRO will be expected, where it chooses to undertake review of services furnished by "shared health facilities," to review those services for the same purposes—to judge appropriateness and quality—that it would review services provided in other health care settings.

Under current law, PSRO's may request authority review ambulatory care services, i.e., those provided in clinics or doctors' offices. However, the committee notes that reliable ambulatory care review methodologies have not as yet been developed. The bill, therefore, requires the Secretary to develop, within two years, effective ambulatory care review methodologies for use by PSRO's. The bill further directs the Secretary, where he finds a PSRO capable of undertaking ambulatory care review, to require the organization to undertake such review not later than two years after it has achieved operational status. The Committee expects that in implementing this requirement, the Secretary

will exercise judgment with respect to the varying capacities of PSRO's and, where appropriate, will establish a reasonable classification of ambulatory care review activities for an organization to undertake. Such classification might include specific categories of services or specific aspects of various service categories. The committee further notes that "ambulatory care services" are those services not rendered by or in an institution. Institutional review, including review of services provided in hospital outpatient departments or emergency rooms, is a requirement of current law and must be conducted before an organization can achieve operational status.

Under current PSRO review provisions, a physician is precluded from reviewing health services provided to a patient if he was directly or indirectly involved in providing the services. Present law further precludes review by a physician of services furnished in any institution, organization, or agency if he or any member of his family has, directly or indirectly, any financial interest in such entity.

The bill would modify these restrictions to permit greater opportunity for physicians participation in PSRO review activities. Under the bill, a physician would not be permitted to review services for which he was directly responsible (rather than directly or indirectly responsible as in present law) or services in an institution in which he or a member of his family has a "significant" financial interest (rather than "any" financial interest, as in present law.) The committee expects that in implementing this provision, HEW will employ the same definition of "significant" financial interest as is currently used in administering medicare.

The bill further provides that arrangements with PSRO's for reimbursement of the costs of review activities are to be made in a manner similar to that provided for medicare intermediaries (which includes provision for advances of funds and payment of administrative costs).

Conclusive Determinations for Payment (Section 5(d))

The committee's bill provides that where a PSRO has been found competent by the Secretary and is performing specific review functions, medical determinations made in connection with such review shall be considered conclusive on those issues for purposes of payment. The bill provides a formal role for the States in the process of establishing and evaluating PSRO review of services provided through the medicaid program. The bill also precludes delegated review in skilled nursing facilities and provides that review of intermediate care facility services will be undertaken by a PSRO only if the Secretary finds that the State is not performing effective review in these facilities.

Under present law, medicare payments and the Federal share of medicaid payments may not generally be made for health care services which a PSRO, in the proper exercise of its duties, has determined to be medically unnecessary or inappropriate. However, the committee believes that it is necessary, in order to avoid the performance of disruptive duplicative reviews by medicare and medicaid agencies, to clarify the scope of the PSRO's authority and the role of the medicaid State agencies.

Accordingly, the bill provides that where a conditionally designed or a qualified PSRO has been found competent by the Secretary to

assume specific review responsibilities and is performing such reviews. a determination as to quality or necessity made in connection with such review would constitute the conclusive determination on those issues for purposes of payment. (Such determinations would be subject to the hearings and appeals provisions of present law.) Medicare fiscal intermediaries and State medicaid agencies would continue to be responsible for other types of reviews and determinations relating to program eligibility, coverage of services, audit, claims payment, fraud and abuse detection, and related activities.

The committee has received comments from a number of States expressing concern over the potential impact of PSRO determinations on State medicaid budgets. The committee has concluded that since substantial State monies are involved it is appropriate that they be given an opportunity to evaluate a PSRO's capability to efficiently and effectively perform review of medicaid services. The bill. therefore, makes provision for the participation of States in the PSRO designation process and in the ongoing monitoring of PSRO review activities.

The bill requires a PSRO to consult with the medicaid State agency in the development of its formal review plan (required as a condition for designation) and in any modification of the plan involving assumption of review responsibility for additional categories of services. The bill provides the States with an opportunity to review and comment on the proposed conditional designation of a PSRO. the change in designation status from conditional to operational, and the assumption by the PSRO of responsibility for long-term care and ambulatory care review. Before the Secretary designates a PSRO or substantially adds to its functions, he is required to take the State's views into account. If his decision differs from the course recommended by the State, he must notify the State of the reason for his decision and allow them additional time to provide further support for their views.

The bill provides that a PSRO's determination shall constitute a conclusive determination for purposes of payment under medicaid only if the PSRO has entered into a memorandum of understanding (approved by the Secretary) with the appropriate State medicaid agency. The purpose of this memorandum is to delineate the relationship between the PSRO and the State agency. The requirement for a memorandum of understanding may be waived only if the State indicates that it does not wish to enter into such an understanding or if the Secretary finds that the State agency has refused to negotiate in good faith or in a timely manner with the PSRO involved.

A State medicaid agency may request a PSRO to include in its memorandum of understanding a specification of review goals and methods (in addition to those required in the PSRO's formal review plan) for the performance of its required functions. If the State medicaid agency and the PSRO are unable to agree on the inclusion of such items, the Secretary would review the requested specification and require that it be included in the memorandum if he determines that the review goals and methods are consistent with titles XI and XIX of the act and do not impair the effectiveness and uniformity of the PSRO's review of health care services under medicare and medicaid. For example, a State might request that a PSRO emphasize the prevention of unnecessary Friday admissions of medicaid patients

for elective procedures not scheduled to be performed until Monday. Your committee notes that the PSRO's application of norms, criteria, and standards would not be affected by this provision: standards for quality, appropriateness and necessity of services would continue to be the same for both programs. If the PSRO found review of weekend admissions was appropriate, it would generally be applied to all patients whose care was reviewed by the PSRO.

The committee intends that the Secretary shall not deny a State agency request solely because the PSRO has not ben utilizing such a requested method or goal for the medicare program or because the PSRO cannot apply the method or goal to the medicare program due to defferences in the patient populations. Rather, the Committee intends that where differences in the patient populations do not preclude uniform review by the PSRO, the Secretary's decision shall be based on his determination as to whether the PSRO can effectively apply such review methods or goals to the review of services provided under both the medicare and medicaid programs in order to ensure that the uniformity of PSRO review under the Social Security Act can be maintained.

The committee intends that any review specified by the State agency which the PSRO performs in accordance with its memorandum of understanding with the agency and pursuant to its review authority until title XI would be fully federally funded. In addition, the bill provides regular Federal matching if a medicaid State agency contracts with a PSRO to undertake additional review responsibilities, provided the State agency formally requests it and the performance of such responsibilities is provided for in an approved medicaid plan amendment. For example, the State agency may request the PSRO to approve so-called administrative days, such as an additional day of hospital stay which may be required because there is no immediately available skilled nursing facility bed.

The bill also provides Federal financial participation to State medicaid agencies for the costs of monitoring the performance of review activities by PSRO's under State monitoring plans which have been approved by the Secretary. It is expected that the Secretary will develop criteria for approval of such plans and that they will not be approved where the proposed monitoring activities duplicate the purposes of PSRO review. The State medicaid agency may include in its plans for monitoring a specification of the performance criteria for judging PSRO effectiveness. Inclusion of such specifications in the State's monitoring plan is not mandated because it is believed that most States during the development and initial implementation of State monitoring of PSRO review will not have such performance criteria developed. However, at such time as the State agency intends to utilize performance criteria for judging PSRO review effectiveness, the Committee expects the agency to discuss the criteria with the PSRO and to amend the State's monitoring plan to include the agreed-upon criteria.

The bill authorizes the State agency to request suspension of the PSRO's authority to make conclusive determinations if in the course of its monitoring activities it develops reasonable documentation that the PSRO review determinations have caused an unreasonable and detrimental impact either on total State medicaid expenditures or on

the quality of care. Within thirty days of receipt of the documentation the Secretary is required to suspend all or part of the PSRO's conclusive determination authority under medicaid. (For example, he may suspend their review of long-term care services, but not hospital services. He may also take similar action with respect to PSRO determinations under medicare if he determines such action is appropriate.) During the suspension period the Secretary is required to conduct a reevaluation of the PSRO's capability to perform review activities and to inform the appropriate agencies, organizations, and congressional committees of any documentation submitted and actions taken.

The bill requires the Secretary to establish procedures and mechanisms governing his relationship to State agencies in connection with their respective responsibilities concerning memoranda of understanding, monitoring, and reevaluations. The Secretary is required to periodically consult with representatives of State agencies and PSRO's. Further, the appropriate State medicaid agency is permitted to be represented on any project assesments conducted by the Secretary. The committee intends that the procedures and mechanisms developed by the Setcretary shall promote smooth working relationships between all parties involved and shall involve a minimum of disruption in the orderly implementation of the PSRO program. The committee further intends that State monitoring activities will become less intensive over time (particularly with respect to PSRO's which are no longer in conditional status) and will focus on problem areas which have been detected in the performance of PSRO review.

The committee is aware of the fact that as PSRO's begin to review services provided in institutional settings other than hospitals, different requirements may be appropriate. Accordingly, the bill prohibits delegated review in skilled nursing facilities since these facilities have generally had far less experience in conducting in-house review activities than hospitals.

(Generally, this prohibition against delegated review would apply only to skilled nursing facilities which were not distinct parts of hospitals or other institutions. If an SNF is a part of a hospital which has a delegation of review authority from a PSRO, it would be the Committee's intent that delegation of review for skilled nursing facility services provided in that institution would be allowed).

Further, PSRO review of care in intermediate care facilities and public institutions for the mentally retarded (services which are paid for only under the medicaid program) would only be undertaken where the Secretary determines that the State is not performing effective review of the quality and necessity of services provided in such facilities. If the Secretary does make such a finding, and the PSRO is required to carry out the review, the committee expects that the PSRO would not delegate review to the intermediate care facility, just as they are prohibited from such delegation to skilled nursing facilities.

Clarification of Sanctions Provision (Section 5(e))

Current law specifies those conditions under which the Secretary may, at the recommendation of a PSRO, withdraw a medical care provider's eligibility to participate in Social Security Act medical care programs where it is determined that it is not willing, or cannot,

carry out its obligations to order and provide only necessary care of acceptable quality.

The bill makes clear that the provision in question applies to any health care practitioner, or any hospital or other health care facility, agency, or organization which is subject to PSRO review.

National Council (Section 5(f))

The bill provides for staggered terms for members of the National Professional Standards Review Council.

Present law provides that the 11 members of the Council shall be appointed for three-year terms and may be eligible for reappointment. The bill would amend this provision. The general term for Council members would continue to be three years, except that for members appointed in 1979, four shall be appointed for a two-year term and three for a one-year term. All members would continue to be eligible for reappointment.

National Council Report (Section 5(g))

Section 5(g) would delete the requirement in present law for an annual report on its activities by the National Professional Standards Review Council and would require instead the submission by the Secretary of a detailed annual report on the PSRO program.

Under the new reporting requirement included in the bill, the Secretary would be required to submit substantially more information concerning the cost and operation of the PSRO program than has previously been required of the National Council. Accordingly, the bill would delete the requirement for the National Council report as duplicative and unnecessary.

Exchange of Data and Information With Other Agencies (Section 5(h))

The committee's bill would expand and clarify the circumstances under which the provision of data or information by PSRO's would not violate the confidentiality requirement of law.

Under present law, any data or information acquired by a PSRO in the exercise of its duties must be held in confidence and may not be disclosed to any person except (1) to the extent that may be necessary to carry out the purpose of the PSRO provisions, or (2) in such cases and under such circumstances as the Secretary shall be regulations provide to assure adequate protection of the rights and interests of patients, health care practitioners, or providers of health care. Interim regulations issued by the Department on December 3, 1976, provide for the disclosure of two types of information acquired by the PSRO:

1. Data and information acquired by the PSRO: (a) which has been published; (b) which has not been identified by the source as confidential; and (c) whose disclosures are not otherwise prohibited by law.

2. Summary statistics aggregated from the Uniform Hospital Discharge Data Set (UHDDS) to the extent that it is not identifiable to an individual patient or health care practitioner.

The bill would expand and clarify those circumstances under which the provision of data or information would not violate the confidentiality provisions to include: (1) provision of data or information by

the PSRO, on the basis of its finding as to evidence of fraud or abuse, to Federal or State agencies recognized by the Secretary as having responsibility for the identification or detection of fraud and abuse activities; such data and information may be provided at the request of the recognized agencies at the discretion of the PSRO; and (2) provision of aggregate statistical data to agencies having responsibility for health planning and related activities under Federal or State law. The data and information furnished to the planning agencies would be provided in the format and manner prescribed by the Secretary or agreed upon by the agencies and the PSRO. Such data and information would be in the form of aggregate statistical data on a geographic, institutional, or other basis reflecting the volume and frequency of services furnished and the demographic characteristics of the population whose services are subject to review by the PSRO. However, the data would not identify any individual.

Data and information made available to Federal or State agencies recognized by the Secretary as having responsibility for identifying and investigating fraud and abuse may not be further disclosed except when the disclosure is made in the course of a legal, judicial, or administrative proceeding. Violation of this prohibition would result in application of the penalty specified in existing law.

The committee has included this provision to facilitate the exchange of data and information with other agencies while at the same time assuring that the confidentiality of patient records will not be violated. The committee has received information that PSRO's which have identified suspected cases or widespread patterns of fraud and abuse have been unable to make the information available to enforcement agencies. The committee also notes that the provision of aggregate statistical data to Federal and State planning agencies will enable those bodies to develop a more accurate picture of medical care patterns in their areas, facilitate planning for future resource needs, and prevent unnecessary duplicative data gathering activities.

The bill also includes a provision to protect patient records from subpena or discovery proceedings in a civil suit. This provision, however, would not preclude the subpena or discovery of originals or copies of the same documents in the possession of others.

Legal Expenses (Section 5(i))

The committee's bill provides for payment of legal fees in connection with the defense of suits brought against a PSRO related to the performance of its functions. The bill would authorize the Secretary to assume responsibility for legal fees incurred in connection with the defense of any suit, action, or proceeding brought against the PSRO or any of its members or employees related to the performance of its functions. While all PSRO's currently have liability insurance which covers such attorneys' fees, this provision would serve as an additional guarantee in the event such insurance is subsequently withdrawn.

Payment of PSRO Expenses (Section 5(j))

The committee's bill would clarify the intent of present law that payment for PSRO expenses is to be made from Federal funds.

Under present law, expenses incurred by PSRO's are payable from medicare trust funds and from funds appropriated to carry out the

other health care provisions of the Social Security Act. The bill would clarify that it is not intended that States or local governmental entities contribute toward these expenses, as they normally must do to receive Federal matching funds under title XIX.

Annual Reports (Section 5(k))

Current law does not require the preparation of a detailed report on the activities, cost, and impact of the PSRO program. The committee believes that this information is necessary to determine the status of program operations, to evaluate the progress of program implementation, and to assess the program's effectiveness.

The bill therefore requires the Secretary to submit annual reports to the Congress by April 1 of each year beginning in 1978 on the administration, impact, and cost of the PSRO program during the preceding fiscal year. The reports must include program data on each PSRO; institutions and practitioners whose services are subject to review; services determined by PSRO's not to meet standards; penalties and sanctions; total costs under titles V, XI, XVIII, and XIX in the implementation of all required review procedures; changes attributable to PSRO activities; progress in adopting and implementing ambulatory review methodogies; results of program evaluation activities; extent to which PSRO's are performing reviews for other private or governmental programs; and legislative recommendations.

Confidentiality of Medical Records (Section 5(l))

The committee's bill addresses the issue of confidentiality of medical records in two ways: (1) it prohibits disclosure to any Federal agent, officer or employee by a Professional Standards Review Organizations of any individually identifiable medical record relating to medical care that is not provided by or paid for by the Federal government (and similarly prohibits Federal access to such records), unless the disclosure or access is specifically authorized by the individual, and (2) it requires the Secretary of HEW, after taking into account the recommendations of the Privacy Protection Study Commission, to submit recommendations to the Congress within three months of the issuance of Privacy Commission report, pertaining to the privacy of patients' medical records, the circumstances under which records may be appropriately examined and the safeguards that need to be established with respect to such examinations and the disclosure of records.

Issues relating to safeguarding the privacy of individually identifiable medical records were of great concern to members of the committee throughout their consideration of H.R. 3. This area represents the one aspect of the bill in which the Committee on Ways and Means and the Committee on Interstate and Foreign Commerce have reported different substantive approaches to the House.

The Committee on Interstate and Foreign Commerce divided their consideration of the issue into two parts: first, what was appropriate policy concerning the access of Professional Standards Review Organizations to individually identifiable medical data, and any disclosure by them of it; and secondly, what was appropriate Federal policy concerning access by Federal employees to individually identifiable medical data, and what rules should govern disclosure in this circumstance.

On the narrower issue relating to PSRO access to individually

identifiable medical data, the committee considered several basic points:

(1) PSRO's must have access to individually identifiable medical data on patients whose care is paid for by Medicare, Medicaid, or the maternal and child health program in order to carry out their function as a group of physicians reviewing the appropriateness and necessity of care;

(2) a PSRO is subject under current law to a strict prohibition against disclosure of information acquired in the exercise of its duties, subject to penalties of a fine of up to $1,000 and imprisonment for up to 6 months, or both.

(3) a PSRO is an organization made up of physicians. Review by a physician of the records of another physician's patients is not uncommon. Both the ethics of the profession and the existence of State statutes assure that the information physicians are privy to on an individual's medical condition is held in confidence.

(4) physicians participating in PSRO's are among those members of the physician community who are most highly experienced and motivated to perform reviews of the appropriateness of medical care; many of these groups of physicians have contracted to perform similar kinds of review with private programs and groups.

(5) programs to control the increasing costs of medical care will be more succesful if peer review of the necessity of care becomes part of all health care programs, whether privately or publicly financed.

The committee was aware of the concern that review of individually identifiable medical data through private arrangements by physicians who are PSRO members might, because of the formal relationship of the PSRO to the Government, result in some Federal access to private patient records unless further protections were placed in the law. Therefore, the committee has strengthened the safeguards protecting the confidentiality of these patient records. The bill prohibits Federal officials from access to PSRO records of identifiable non-Federal funded patients without the express consent of these patients. Nor can PSRO's disclose such identifiable data to Federal officials without specific patient consent. This amendment would allow the PSRO's to perform review of non-Federal patients, if the organization's members choose to do so, while protecting the information from Federal agents.

The committee believes that PSRO's should not be discouraged from performing review of private patients, nor should the physicians of a PSRO be subject to restrictions not otherwise placed on comparable review bodies. Such PSRO review is supportive of efforts for hospital cost containment. These cost containment provisions cut across all patients and not just those whose services are reimbursed from Federal funds. Additionally, there are currently States, such as Connecticut, which require by Law PSRO review of all hospital patients. Many major companies, unions, and health insurers have contracted with or are now negotiating contracts with PSRO's to perform review in the anticipation of reducing unnecessary utilization and costs. The amendment will allow this development. The committee is concerned that the amendment reported by the Ways and Means Committee, how-

ever, would tend to obstruct review by PSRO's of non-Federally financed patients by requiring specific, detailed and time limited patient consent which is not required for any other review body. The PSRO would continue to be governed by any applicable State laws governing access and disclosure, of course, just as other review groups would be.

In regard to the broader issue of access by Federal employees, agents or officers to individually identifiable medical data, the committee studied carefully the provision banning access to these records that was adopted by the Ways and Means Committee. This committee shared with the members of that committee a strong concern for the right of the patient to privacy. We were also concerned, however, that vital activities of the Government to protect the health and safety of the public should not be impaired unnecessarily.

Because of the importance of the issue, the Subcommittee on Health and the Environment of the committee reopened H.R. 3 for consideration after it had initially been reported to the full committee, and received testimony on this issue from representatives of HEW, the Department of Defense, the Consumer Product Safety Commission, and the Environmental Protection Agency, among others. The committee is including a transcript of the testimony of these witnesses in the appendix of this report, since it was received too late in the process to be included in the hearing record. Also included in the appendix are the communications that were received from the Department of Health, Education and Welfare and the Office of Management and Budget on this issue. This testimony, and numerous communications from respected medical care professionals from the Mayo Clinic, from various schools of public health, from cancer research centers, and from persons who are active in the field of environment and occupational health, from many agencies of the Executive Branch, and others, convinced the committee that balancing concerns of privacy versus concerns for protection of the public health were exceedingly complex and required extensive and detailed examination to assure that damaging effects would not unintentionally be the result of any language adopted.

The committee reluctantly reached the conclusion that the amendment adopted by the Ways and Means Committee would seriously undermine existing critical public health, cancer research, and environmental and occupational safety programs, and, in some instances could even preclude necessary action in life threatening situations.

A few of the vital program activities which would be significantly altered, if not terminated, by this amendment, include:

1. *Epidemic investigation.*—Frequently numerous records must be reviewed rapidly; individuals at risk identified, found, and offered appropriate protective measures or treatment; and community control programs planned. Recent examples include the hundreds of potential contacts to Legionnaire's disease; St. Louis Encephalitis epidemics in four Southeastern States in 1975; and a nationwide exposure of patients to bacterially contaminated intravenous fluids.

2. *Epidemiologic research.*—Epsecially that related to the cause and course of illness over a long period of time. Again, individuals who at some past point in time may have been exposed to a toxic or carcinogenic agent, must be identified, found, examined, and treated if necessary. Recent examples include studies linking the use of DES

in pregnant women to vaginal cancer in their daughters; vinyl chloride work exposure to an increased risk of liver cancer; and x-ray treatment two or three decades ago to an increased risk of thyroid cancer.

3. *Communicable Disease Control.*—Even such important ongoing programs as immunization and venereal disease control would be affected. In immunization programs it is often necessary to review a child's record to see what vaccines may be needed, not only routinely, but in the face of an epidemic control effort. Penicillin resistant gonorrhea, a major new VD threat to this country, can only be controlled by identifying and treating all exposed individuals before they can transmit this organism to others.

4. *Laboratory records.*—Certain findings, which may result from even routine testing, such as evidence of hepatitis, syphillis, and typhoid require immediate identification and follow-up not only for the protection of the individual, but the public as well.

5. *Unpredictable events.*—Examples include the recent life threatening situation of a young boy with Lasa Fever, where the only way to prevent his death was to identify the very small number of travellers to Africa who had Lasa Fever and who could provide protection to the child on a few hours notice. Another recent example is that of Guillain-Barre syndrome associated with swin flu vaccine. All known cases of GB in the nation had to be quickly identified, seen, and vaccine history established so that a scientifically valid decision could be made as to the possible relation between immunization and that syndrome.

6. Other important health activities including the monitoring of new drug research by FDA.

These are only some examples. Often these activities are typified by a need to examine individual records in order to find individuals who received certain treatments or exhibited certain symptoms. Only after these individuals are identified can they be located and their consent for further study be obtained. Only after they have been identified and located can they make a judgment which is truly informed consent concerning further access to medical information about them.

The issue of individual protection is, of course, an extremely important one. It was for this reason that the Congress established a Privacy Protection Study Commission two years ago to study the full implications of this problem. Their report is to be issued on July 12. The committee has been informed that the Report includes a detailed series of recommendations which will safeguard privacy with respect to medical records, but not cripple research and critical public health activities by an inappropriate and even unsafe prohibition of necessary access. Translating this Report into legislation will require careful deliberation and time-consuming work. Further, the members of the Congress and the general public should have the assurance that the legislation that is developed has been offered for review and comment by the public. It is for this reason that the committee has included in its bill a requirement that the Secretary submit to the appropriate congressional committees, within three months of the issuance of the final report of the Privacy Protection Study Commission, a report and legislative recommendations for appropriate procedures to maintain the confidentiality of all individually identifiable medical records, and to pro-

vide for appropriate safeguards against unwarranted inspection or disclosure of such records.

Medical Officers (Section 5(m))

The bill would include medical officers in American Samoa, the Northern Mariana Islands and the Trust Territory of the Pacific Islands in the PSRO program. In these areas medical officers rather than doctors of medicine provide medical care. The bill would therefore permit medical officers licensed to practice medicine in these localities to participate in the PSRO program. These individuals may not, however, serve on the National Council or make any final determinations with respect to medical necessity or appropriateness of care provided by a duly licensed doctor of medicine or osteopathy.

Payment for Review of Part B Services Provided by Hospitals (Section 5(n))

Public Law 94–182, enacted on December 31, 1975, included an amendment to the medicare program which was designed to equalize reimbursement for PSRO hospital review activities whether such review was carried out by a hopsital under delegation from a PSRO or by the PSRO itself. Previously, only delegated review activities could be funded out of the medicare trust funds. Under the new law, PSRO expenses in carrying out nondelegated review for hospital services covered under medicare part A or medicaid or the maternal and child health program would also be reimbursed through this mechanism. The law did not, however, provide for similar funding for PSRO review of hospital services covered under medicare part B.

Accordingly, the bill corrects this oversight by providing that funding for delegated review activities for services provided by a hospital which are covered under medicare part B shall be made from the medicare trust funds.

Statewide Councils (Section 5(o))

The bill extends the protection currently provided to members and employees of a PSRO from criminal prosecution or civil liability when carrying out PSRO functions to members and employees of Statewide Professional Standards Review Councils.

Issuance of Subpenas by the Comptroller General (Section 6)

The bill would give the Comptroller General of the United States the power to sign and issue subpenas to gain information regarding health programs authorized under the Social Security Act.

Currently, the Comptroller General of GAO does not have the statutory authority, under the Social Security Act, to issue subpenas in connection with GAO investigations into health programs authorized by that Act. In a December 29, 1976, letter to the committee, which was in response to an inquiry concerning Social Security Act subpena power for the General Accounting Office, the Acting Comptroller General stated that:

> From the overall perspective, we believe that the subpena power in question would be a useful tool. In all probability, the mere existence of such a power would be sufficient to preclude problems in most cases and, in our opinion, resort to its use would be relatively infrequent. We would thus favor the inclusion of subpena authority in the anticipated new legislation.

The bill would give the Comptroller General of GAO the power to sign and issue subpenas in order to gain information and facilitate review of medicaid, and the maternal and child health programs particularly with respect to investigations of fraudulent and abusive practices. In connection with GAO's statutory functions including investigations, examinations, and auditing, subpenas could be issued to gain access to pertinent books, records, documents, or other information.

Under resistance or refusal by an individual to obey a subpena, the bill would authorize the Comptroller General to request a court order requiring compliance.

In granting GAO the power to subpena books, records, and documents, the committee is aware that the personal medical records of beneficiaries and recipients could be subject to subpena. In the context of the provision, personal medical records are defined to mean any information relating to an individual's medical or mental condition or treatment that is acquired by GAO in the course of its investigations into Social Security Act health programs, in a form that could identify the individual.

The committee strongly believes that confidentiality of personal medical records must be protected and has, therefore, placed strict controls on the disclosure of such information by GAO personnel. The bill would prohibit the disclosure of any personal medical records in the possession of the GAO to any person except those GAO employees whose official duties require seeing them. GAO personnel illegally disclosing such records would be subject to a $1,000 fine, six months imprisonment, or both; and if convicted, prosecution costs. In addition, the bill would exclude the copies of all personal medical records in GAO possession from subpena or discovery proceedings in a civil action. This exclusion, however, would not preclude the subpena or discovery of originals or copies of the same documents in the possession of others.

The bill would permit GAO disclosure of personal medical records only to Federal or State agencies authorized to investigate cases or patterns of fraud and abuse under Social Security Act health programs. Prior to such disclosure, however, the Comptroller General must determine that such records actually reveal evidence of fraud and abuse.

Suspension of Practitioners Convicted of Medicare- or Medicaid-Related Crimes (Section 7)

The committee's bill requires the suspension of physicians or other individual practitioners from participation in medicare or medicaid if such practitioner has been convicted of a program-related criminal offense.

The committee has included this provision in response to the concern that some program violators have been permitted continued participation, often without interruption, in Federal health care programs. The committee feels that misuse of Federal and State funds is a very serious offense and that those convicted of crimes against the programs should not be permitted continued and uninterrupted receipt of Federal and State funds. The committee believes that this threat of suspension, together with the upgraded penalties authorized under the bill, will serve as a significant deterrent to fraudulent practices under medicare and medicaid.

Under current law, physicians or other individual practitioners who have been convicted of an offense related to their participation in medicare or medicaid are not automatically suspended from these programs and can continue to receive payment therefrom. The Secretary may suspend Federal payment to a person who has falsified information related to a request for payment. The Secretary may also suspend a person who bills the program for charges substantially in excess of the person's customary charges or who has furnished services found to be substantially in excess of an individual's need, to be harmful, or to be of grossly inferior quality.

The bill requires the Secretary to suspend from participation under medicare, a physician or individual practitioner who he determines has been convicted of a criminal offense related to such individual's involvement in medicare or medicaid. To permit case-by-case determinations, the suspension would be for such period as the Secretary deems appropriate and no medicare payment could be made for any item or service furnished by such individual during this period. Individuals subject to suspension are those who are convicted on or after the date of enactment of the law or within such period prior to enactment as the Secretary may specify in regulation. Provision is made for appropriate notice to the individual and the public and hearing and judicial review of the Secretary's determination. In any case where the Secretary suspends a practitioner from participation in medicare he is required to promptly notify every State medicaid agency and the appropriate State or local licensing authority.

Whenever a State medicaid agency is notified by the Secretary that a practitioner has been suspended under medicare, it shall suspend such individual from participation in medicaid. This is intended to prevent practitioners from moving from one State to another in order to avoid the effect of the suspension. To conform the timing of suspensions, the medicaid suspension period shall not be less than the suspension period applicable to the individual under medicare. No medicaid program payments may be made for services provided by such individual during the suspension period.

In his notification to the licensing authority the Secretary shall request that investigations be made and sanctions be invoked, as deemed appropriate in accordance with the State's law and policy. The Secretary and Inspector General would be notified of whatever action, if any, is taken by these authorities.

The committee was concerned that imposition of this suspension, under certain unusual circumstances, could deny adequate access to medical care to persons eligible for services under medicare or medicaid. To ensure that this would not occur, the bill provides two remedies. First, the bill would authorize the Secretary to designate a community as a health manpower shortage area (as defined under title III of the Public Health Service Act) for purposes of placement of National Health Service Corps personnel, if he determines that imposition of a suspension would leave those residents of the area eligible under medicare or medicaid without adequate access to health services. Second, the bill permits the Secretary, on the request of a

State, to waive a practitioner's suspension under the State's medicaid program. The committee intends that such waivers be granted sparingly. It is expected that waivers will only be approved where imposition of the suspension would deny a community of needed medical service because of the shortage of practitioners in that area and no National Health Service Corps personnel have been assigned.

Disclosure by Providers of Owners and Certain Other Individuals Convicted of Certain Offenses (Section 8)

The committee's bill requires all institutional providers of services participating in medicare, medicaid, or title XX State social service grant programs to disclose the names of owners and certain other individuals who have been previously convicted of fraud against any one of these programs.

Current disclosure of ownership provisions do not require institutional providers of services and other agencies and organizations certified to provide services under titles XVIII and XIX of the Social Security Act to disclose information about criminal records any of their owners and managerial employees may have. Similar information is also not required from institutional providers participating in title XX of the Social Security Act, a number of whom are also certified to provide services under medicare and medicaid. Existing procedures for determining this information are inadequate, time-consuming, and have permitted individuals previously convicted of such offenses to continue ownership or management in participating facilities or become owners or managers in other participating facilities without program administrators being aware of an individual's past activities which might have a bearing on a facility's future performance.

Lack of adequate disclosure of these individuals is an additional restraint on HEW's attempts to investigate and control program abuse. It has hampered and restricted Department efforts to limit the participation of those facilities and other organizations providing services under titles XVIII, XIX, or XX that are partially owned or controlled by persons convicted of criminal offenses against the programs.

Even when such individuals can be identified by the Department of HEW or State administering agencies, it is difficult under existing procedures to limit participation of facilities owned by these persons. Currently, no provisions exist to enable the Secretary of HEW or a State agency to refuse to enter into or to terminate provider agreements or contracts with institutional providers or other organizations owned by such individuals as long as existing conditions for participation under titles XVIII, XIX, or XX are met.

The result of the failure of the current law to provide procedures whereby facilities owned by persons who have previously been convicted of fraud aginst Medicare or Medicaid has been that these persons continue to receive payments from the programs. A recent report in the June 11 edition of the New York Times provides an example of this situation.

BERGMAN RESUMES NURSING HOME ROLE

FILING OF APPEAL VOIDS REVOCATION OF OPERATING LICENSE

(By Edith Evans Asbury)

Bernard Bergman, who was convicted in Federal and state courts of Medicaid fraud in the operation of a string of nursing homes, is back in the nursing home business, operating the Park Crescent Nursing Home in Manhattan.

Mr. Bergman's license to operate the Park Crescent was ordered revoked by state health authorities after he was convicted of Medicaid frauds involving more than $1.2 million and of tax frauds, including falsification of the books of the Park Crescent. He is appealing the revocation order.

The nursing home, at Riverside Drive and 87th Street, has 500 patients for which Medicaid pays approximately $20,000 a day....

* * * * * * *

Dr. Robert P. Whalen, State Commissioner of Health, was also distressed.

"It is terrible that he is back in the business," he said. "I am sure all of those involved in trying to improve the care of the elderly will feel terrible to learn of it."

He added that he felt "helpless" at being unable to revoke the license "until the proper time expires" for Mr. Bergman to appeal, and was asking his legal staff "to continue to work with the Attorney General to see what other legal remedies might be available."

"This points up the need," Dr. Whelan said, "for legislation we have ben seeking for two or three years which would prohibit felons from operating nursing homes, together with necessary procedural safeguards."

As this case illustrates, even criminal conviction is not sufficient to exclude an individual from the nursing home industry or the Medicaid system. Lengthy state administrative procedures must also be carried out, vulnerable to delaying litigation. The problem would be compounded under present law whenever a provider convicted in one state continues to operate in another. Then the speedy removal of the provider from the Medicaid program would be almost impossible. Conferring the proposed powers on the Secretary would ensure that providers who have flagrantly abused the system will not be able to exploit the delays in state administration processes to continue their profiteering.

In order to deal with this problem, as a condition of participation, certification, or recertification under titles XVII, XIX, or XX of the Social Security Act, the bill would require all institutional providers of services, or other agencies, institutions, or organizations to disclose to the Department of Health, Education, and Welfare or to the appropriate State agency the names of its owners, officers, direc-

tors, agents, or managing employees who have been convicted of a criminal offense against medicare, medicaid, or State social service grant programs. The bill specifies that when an application requesting such participation or certification contains the names of any such previously convicted individual, the Secretary of HEW or the State agency may refuse to enter into an agreement or contract with the institution to provide services under titles XVIII, XIX, or XX. In addition, the bill specifies that the HEW Inspector General must be informed of any such applications received and of any actions taken on them. The bill would also permit the Secretary or appropriate State agency to terminate existing provider agreements or contracts under titles XVIII, XIX, or XX, if the names of such individuals have not been disclosed, as required.

In applying the disclosure requirements to convicted persons who are officers, directors, agents, or managing employees of the institution, as well as to convicted persons with ownership interests, the committee feels that this parallel requirement is necessary in order to ensure that program administrators are aware of the renewed involvement of these persons in participating institutions.

The bill would specifically define the term "managerial employee" to mean a person who exercises operation or managerial control over the institution or one who directly or indirectly conducts the day-to-day operations of the institution including, but not limited to, an institution's general manager, business manager, administrator, and director. The bill would define the owner of an institution as any person who has a direct or indirect ownership or control interest of at least five percent in the institution.

Federal Access to Records (Section 9)

Under present law, State plans under medicaid are required to provide for agreements with every person or institution providing services whereby such persons or entities will keep complete records of services provided under the program and furnish the State agency, upon request, which information regarding any payments claimed under the program. Similar access to records by the Secretary is not required. The committee feels this could hamper Federal efforts to obtain information necessary to examine potential instances of fraudulent and abusive activities. The bill therefore specifically permits the Secretary to have access to records of persons or institutions providing services under medicaid in the same manner presently provided to State medicaid agencies.

Claims Processing and Information Retrieval Systems for Medicaid Programs (Section 10)

The bill permits States to send explanation of benefits forms to a sample of medicaid recipients and still be entitled to increased Federal matching for operation of approved management information systems. The bill specifies that there would be no explanation of benefit forms in the case of services which are confidential in nature.

Present law authorizes an increase in Federal matching to 75 percent toward the costs of operating an approved medicaid claims processing and information retrieval system if the system provides explanation of benefits information to all recipients. The committee has been informed that this strict requirement for explanation of

benefit forms in every case has limited the growth of approved systems. In addition, questions have been raised about the cost effectiveness of this requirement because of the high volume of claims for services provided under medicaid.

The bill therefore modifies the current requirement by permitting the increased matching if the system provides explanation of benefits information to a sample group of recipients. The committee expects that the samples will be of sufficient size and sufficiently representative of the population served and the services rendered to enable the identification of any questionable or unusual patterns. It is the intention of the committee that all confidential services, and services integrally related to a confidential service, be deleted from the explanation of benefit forms in order to assure privacy for the medicaid patient. States will be expected to institute appropriate safeguards to accomplish this.

The committee notes that this change in the medicaid statute does not constitute a new entitlement to higher Federal matching, but merely increases the workability of the existing provision.

Medicaid As Payor of Last Resort (Section 11)

The bill precludes Federal matching payments for expenditures under medicaid for services which a private insurer would have an obligation to pay except for a provision of its insurance contract which has the effect of limiting or excluding such obligation because the individual is eligible for or receiving medicaid.

Under current law, States or local agencies administering medical assistance plans are required to take all reasonable measures to ensure that third parties legally liable to pay for any medical care rendered to medicaid recipients meet their legal obligations. However, some private insurance policies contain a provision that limits the insurance companies' liability to the amount not covered by medicaid. In some cases, State insurance commissioners have not taken action to stop this practice. When it occurs, the medicaid program is forced to assume the costs despite the existing subrogation requirement.

The bill would provide an incentive to States to stop this practice by stopping all Federal matching payments for expenditures made under the plan for care or services provided to the extent the private insurer (as defined by the Secretary) would have been obligated to pay except for a provision of its contract which has the effect of limiting or excluding such obligation because the individual is receiving assistance under medicaid.

Study and Review of Medicare Claims Processing (Section 12)

The bill directs the Comptroller General to conduct a comprehensive study of the claims processing system under medicare for the purpose of determining what modifications should be made to achieve more efficient claims administration.

Under medicare part A, groups or associations of providers can nominate an organization to serve as a fiscal intermediary between the providers and the government. An individual member of an association or group of providers that has nominated one organization as intermediary may select some other organization if this is satisfactory to the organization and HEW, or alternatively it may elect to

deal directly with the government. HEW may not enter into an agreement with an organization unless it finds that such agreement is consistent with efficient and effective administration. The Social Security Administration has selected 10 hospital-nominated organizations to serve as intermediaries. This includes the Blue Cross Association which carries out its claims administration activities through 73 statewide and local Blue Cross Plans. Under medicare part B, the Secretary contracts with carriers to perform claims processing activities. Carriers are selected to serve specified geographic areas. There are 47 carriers, including 32 Blue Shield plans. Both intermediaries and carriers are reimbursed on a cost basis for carrying out their activities.

A reexamination of the administrative framework of the medicare program in order to assess the need for possible modifications is desirable.

The bill therefore directs the Comptroller General to conduct a comprehensive study and review of the administrative structure established for processing claims under medicare. The study is to determine whether and to what extent more efficient claims administration could be achieved by reducing the number of carriers and intermediaries, making a single organization responsible for processing claims under parts A and B in a particular geographic area, paying for claims processing on the basis of a prospective fixed price, providing other types of incentive payments for efficiency, or by other modifications in existing structure and procedures. The Comptroller General would be required to submit a report containing his findings and recommendations to the Congress by July 1, 1979.

Abolition of Program Review Teams Under Medicare (*Section 13*)

The bill repeals the provisions in current law relating to program review teams.

The Social Security Amendments of 1972 included a provision authorizing the Secretary to suspend or terminate medicare payments to a supplier of services found to have abused the program. In the case of such a suspension or termination, Federal participation was also to be withheld for medicaid payments made in behalf of such supplier. This provision was included to permit HEW to bar future payments to suppliers who have made a practice of furnishing inferior or harmful supplies or services, engaging in fraudulent activities, or consistently overcharging for their services.

To assist him in making determinations under this section, the Secretary was required to establish program review teams in each State. These professionally-based bodies were to advise the Secretary concerning such matters as whether excessive, harmful, or grossly inferior care is being rendered to patients. The functions of program review teams relating to the review of the quality and appropriateness of services are essentially duplicative of the functions required to be performed by PSRO's.

The bill therefore deletes the requirements in current law pertaining to the establishment and responsibilities of program review teams with the expectation that the appropriate PSRO will instead be available to advise the Secretary in cases that require the application of professional medical judgment.

Amendments Relating to Fiscal Intermediaries (Section 14)

The bill authorizes the Secretary, after taking into account the provider's nomination and after applying the appropriate standards and criteria required under this section, to assign and reassign providers to available intermediaries. He is also authorized, after applying the required standards and criteria, to designate regional intermediaries or a national intermediary with respect to a class of providers. The bill requires the Secretary to develop standards, criteria, and procedures for evaluating the adequacy of intermediary performance, and the efficiency and effectiveness of program administration, and to apply such standards and criteria in making determinations as to the participation and role of intermediaries in the program. Intermediaries are required to provide access by the Secretary to necessary data and information.

Under part A of medicare, groups or associations of providers of services, i.e., hospitals, extended care facilities, and home health agencies, can nominate an organization to act as a fiscal intermediary between the providers and the Secretary. An individual member of an association or group of providers which has nominated one organization as intermediary may select some other organization as its intermediary if this is satisfactory to the organization and the Secretary, or alternatively, it may elect to deal directly with the Secretary. The Secretary may enter into an agreement with a nominal organization only if he finds that this would be consistent with efficient and effective administration and that the organization is able and willing to assist providers in the application of safeguards against unnecessary utilization of services.

The provision giving providers considerable latitude in their selection of intermediaries was included in the original medicare law in order to facilitate a smooth transition to the new health insurance program. While recognizing the contribution intermediaries generally have made toward the successful implementation of the medicare program, there is some potential for conflicts of interest exists under a system where intermediaries are responsible for fulfilling title XVIII requirements on the one hand, while on the other, their continued role as intermediaries is often contingent upon the providers' satisfaction with them. While there is no implication that such conflicts are pervasive, or that many intermediaries have been lax in performing their functions, there is some evidence, particularly in the case of home health agencies, of ineffective intermediary performance.

The results of some of the current measures now used to evaluate intermediary performance are not always reliable indicators of performance. For example, for the quarterly reporting period July–September 1976, the adjusted cost per claim ranged from $2.73 to $7.21 with a weighted national average of $4.50. For the same time period, the adjusted number of claims per 100 man hours ranged from 155 to 399 with a weighted national average of 242. Existing performance measures have not been sufficiently refined to determine the extent to which the variances reflect actual differences in costs rather than differences in accounting and reporting practices. Even where cost differences occur, lower costs do not necessarily imply a more efficient and effective operation. Other factors, such as the

types of claims processed, are relevant to the assessment of performance. It is imperative that more precise and uniform standards and criteria for evaluating the performance of intermediaries in the administration of the program need to be developed and that such objective standards and criteria need to be applied by the Secretary in making determinations with respect to the renewal or termination of agreements, as well as the assignment of providers, and the designation of regional or national intermediaries.

The bill therefore includes provisions designed to permit improvements in the administration of the hospital insurance program. In the interest of efficient and economical program administration, the bill authorizes the Secretary to assign and reassign providers to available intermediaries. While the bill retains the present provision of law allowing a provider to designate a preference through the nomination process the Secretary would not be bound by a provider's choice. His decision must be based on a finding made, after applying the required standards and criteria with respect to the intermediary chosen by the provider, that in this particular instance reassigning a provider to another intermediary will result in more effective and efficient administration of the program. The bill requires that if the Secretary makes a determination which is not in accord with the provider's preference, the provider and his chosen intermediary be given a full explanation of the reasons for the Secretary's determination, and the intermediary be provided with an opportunity for a hearing.

The bill also authorizes the Secretary to designate regional intermediaries or a national intermediary to perform the required functions with respect to a class of providers (such as home health agencies) if he determines, after applying the appropriate standards and criteria to all affected intermediaries, that such designation would result in more effective and efficient administration. Such designations may not be made until the affected providers and intermediaries are provided with a full explanation of the reasons for his determination and the intermediaries are granted an opportunity for a hearing.

The bill further provides that determinations by the Secretary with respect to the assignment or reassignment of a provider to an intermediary other than the one nominated by the provider and the designation of a regional or national intermediary would be subject to judicial review in accordance with the appropriate provisions of the Administrative Procedures Act, in order to assure that in making such determinations the Secretary complies with the requirements of due process applicable to such administrative decisions. It is expected that such determinations will not be implemented, in the event an intermediary contests the Secretary's determination, until such time as the affected intermediary has exhausted the appeal rights available to it under this bill.

The bill requires the Secretary to develop standards, criteria, and procedures to enable him to evaluate intermediaries' performance of the claims processing and other related functions required to be performed by them and to permit him to make objective determinations with respect to the efficiency and effectiveness of program administration. The Secretary is required to develop such standards, criteria and procedures by October 1, 1978, and apply them in making determinations relating to the renewal or termination of agreements with in-

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termediaries, the assignment or reassignment of providers and the designation of regional or national intermediaries beginning on that date.

The bill further requires that agreements with intermediaires provide for access by the Secretary to all data, information and claims processing operations as he may find necessary to enable him to perform his required functions.

Disclosure by Providers of the Hiring of Certain Former Employees of Fiscal Intermediaries (Section 15)

The bill would require a provider of services under the medicare program to notify the Secretary promptly of its employment of an individual who at any time during the preceding year was employed in a managerial, accounting, auditing or similar capacity by a fiscal intermediary or carrier who had served that provider.

In certain cases in the past providers have specifically recruited and employed personnel of the fiscal intermediary serving it, apparently in order to assist the provider in justifying questionable accounting and cost reporting procedures. This type of hiring practice potentially subverts the integrity of the intermediary provider relationship, including the integrity of the auditing process. The Department of HEW is expected to utilize the information gained under the notification required under the bill to discourage such practices, especially when such information suggests possible conflict of interest situations.

Providers who hire employees of fiscal intermediaries, particularly accountants and auditors who have been involved in auditing that provider, should be on notice that such practices will be followed closely.

Payment for Durable Medical Equipment (Section 16)

The bill would modify the present methods for reimbursing medicare beneficiaries for expenses incurred in obtaining durable medical equipment. The intent of this modification is to reduce program expenditures and assure greater protection for beneficiaries against the need to pay excessive rental fees.

Present law provides for reimbursement under part B of medicare for expenses incurred in the rental or purchase of durable medical equipment used in the patients' home. The beneficiary has the option to rent or purchase such equipment. In the case of purchase, reimbursement is generally made in monthly installments equivalent to amounts that would have been paid had the equipment been rented.

Reimbursement may be made on a lump-sum basis for purchased equipment that is relatively inexpensive, i.e., items for which the reasonable charge is $50 or less.

Where a beneficiary elects to rent equipment, medicare will continue to reimburse him for 80 percent of his rental expenses as long as his medical need for the equipment continues. A study conducted by GAO showed that rental payments under the program for durable medical equipment require over an extended period of time frequently exceeded, by a substantial amount, the reasonable purchase price of the equipment. Moreover, beneficiaries were also overpaying for equipment since they are liable for the 20 percent coinsurance amount.

The Social Security Amendments of 1972 added provisions to the law to help avoid unreasonable expenses to the program and to beneficiaries resulting from prolonged rentals of equipment. These provi-

sions authorized the Secretary to experiment with alternative reimbursement mechanisms, including the use of lease-purchase arrangements and lump-sum payments for purchased equipment where it could be determined in advance that the use of the equipment would be medically necessary for an extended period of time. Although the Department has not conducted the extensive experimentation contemplated by the legislation, sufficient evidence is available to indicate that changes in the reimbursement methods are needed to deal with the long-standing problems arising under the durable medical equipment provision of law.

To remedy these problems, the bill makes several changes in the methods used in reimbursing beneficiaries and suppliers for durable medical equipment. First, the bill requires the Secretary to determine, on the basis of medical evidence, whether the expected duration of medical need for the equipment warrants the presumption that purchase would be less costly or more practical than rental, and would not impose financial hardship on the beneficiary. Where such a presumption can be made, the Secretary would require purchase of the equipment and would provide reimbursement on the basis of a lump-sum payment or on the basis of a lease-purchase arrangement. Since lease-purchase would generally be the preferred mode of payment, and would ordinarily provide the greatest degree of cost-effectiveness for the program and the beneficiary alike, the bill specifically directs the Secretary to take steps to encourage suppliers, through whatever administrative arrangements he finds feasible and economical, to make equipment available to beneficiaries on a lease-purchase basis.

Secondly, the bill retains the provision in existing law which authorizes the Secretary to waive the 20 percent coinsurance requirement with respect to the purchase of used durable medical equipment whenever the purchase price is at least 25 percent less than the reasonable charge for comparable new equipment.

Funding of State Medicaid Fraud Control Units (Section 17)

The committee's bill authorizes 90 percent Federal matching payments for fiscal years 1978–1980, for the establishment and operation of State medicaid fraud control units.

The committee is concerned that sufficient efforts have not been made to date to identify and prosecute cases of medicaid fraud in a number of States. In the absence of effective investigative units, individuals engaging in fraudulent practices are able to continue their activities virtually unchecked. Sections of the bill provide for criminal sanctions and suspension actions for those convicted of medicaid fraud. However, strengthened penalties must be coupled with strengthened investigatory powers in order to assure that those engaging in criminal activities are identified and prosecuted. Further, the combination of rigorous enforcement and criminal sanctions should serve as a deterrent to similar practices by other providers and practitioners.

During the hearings held on this legislation, testimony was presented showing that where a separate investigative entity has been established, the rate of prosecutions and convictions has been substantially increased. For example, there was testimony that in the period from 1970 to January 1975, there was not a single prosecution in New York State for medicaid fraud arising out of the operation of a nursing home. In January 1975, a special office was established to ex-

amine the rapidly growing scandal in the nursing home industry. As a result of its investigations, grand juries have indicated more than 90 individuals mostly for medicaid fraud. To date, there have been 27 convictions and the office has forced payment of more than four million dollars in criminal restitution—an amount several hundred thousand dollars in excess of the office's first year budget. The committee was particularly impressed with the organization and operation of the New York Special Prosecutor's Office, and believes it constitutes a model for anti-fraud efforts in other States.

When the committee learned that a number of States are interested in establishing or strengthening existing medicaid fraud and abuse control units, it wished to encourage efforts similar to the New York unit. However, in view of the fiscal constraints being experienced by many of the States, the current 50 percent administrative matching rate has not served as a sufficient incentive to the establishment or expansion of such units. The committee believes that a short-term increase in the Federal matching rate of 90 percent will enable States to establish effective investigative entities and expand existing efforts. After these units have been operational for a few years, their recoveries from prosecutions should begin to equal or exceed the cost of operation. Therefore, under the bill, the increased matching rate would only be in effect for three years.

The bill, therefore, provides for 90 percent Federal matching for fiscal years 1978–1980 for the costs incurred in the establishment and operation (including the training of personnel) of State fraud control units meeting specified requirements, subject to a quartely limitation of the higher of $125,000 or one-quarter of one percent of total medicaid expenditures in such State in the previous quarter.

To be eligible for the increased matching rate, the State medicaid fraud control unit must be a single identifiable entity of State government which the Secretary certifies (and annually recertifies) as meeting specific requirements. Such entity must be a unit of the office of the State Attorney General or of another department of State government which has statewide prosecutorial authority (unless it is located in a State where the State constitution prohibits prosecution by a Statewide authority; then, to receive the higher matching, the unit must have procedures acceptable to the Secretary of HEW to refer suspected criminal violations to the appropriate prosecuting authorities, and to assist with the prosecutions).

The unit is required to be separate and distinct from the State medicaid agency. The entity must also conduct a statewide program for the investigation and prosecution of violations of all applicable State laws relating to fraud in connection with the provision of medical assistance and the activities of medicaid providers. Such unit is not however required to examine potential instances of recipient fraud; this function may continue to be the responsibility of the State medicaid agency. The fraud and abuse control unit must have procedures for reviewing complaints of the abuse and neglect of patients by health care facilities, and, where appropriate for acting on such complaints or for referring them to other State agencies for action. The entity is required to provide for the collection, or referral for collection, of overpayments made to health care facilities. In order to promote effective and efficient conduct of the entity's activities, it must be organized in a manner to achieve these objectives and it must employ

auditors, attorneys, and investigators and other necessary personnel. The entity is further required to submit an application and annual report containing information deemed necessary by the Secretary to determine whether the entity meets these requirements. To facilitate implementation of this section, the Secretary is required to issue regulations within 90 days of enactment.

The committee wishes to emphasize the need for the employment of highly skilled auditors, attorneys, and investigators specially trained in the area of medicaid fraud. The committee has received substantial evidence of the complex schemes employed by those engaging in fraudulent activities and notes that the only way such practices can be effectively addressed by utilizing persons specially skilled in uncovering these activities.

The committee intends that the increased matching rate authorized under this section be made available to existing State fraud control units providing they meet (or appropriately modify their operation so as to meet) the specified requirements.

Report on Home Health and Other In-Home Services (Section 18)

The committee's bill would require the Secretary of Health, Education, and Welfare to report to Congress on home health and other in-home services authorized under title XVIII, XIX, and XX of the Social Security Act.

The committee is concerned that, with respect to home health and in-home services authorized to be provided under medicare, medicaid, and title XX social service programs, more effective methods need to be developed to assure the quality of services provided and efficiency in administration of the programs, and more effective efforts to curb fraud and abuse. While it is understood that there are, by necessity, differences among these programs in entitlement to the services and the types of services covered, it is the feeling of the committee that any efforts to develop methods of quality assurance and administrative efficiency should, where possible and practical, provide for coordination between the programs, particularly with respect to requirements for providers of services and reimbursement methods.

The Secretary is, therefore, directed to submit within one year a report to the appropriate committees in Congress analyzing all aspects of the delivery of home health and in-home services authorized under these titles. Further, since the intent of this legislation is to facilitiate establishment of a set of specific, enforceable standards in the programs to assure high quality home health services and the protection of the health and safety of recipients of such services, the Secretary is required to report on regulatory changes needed and to recommend appropriate statutory changes with respect to quality assurance and administrative efficiency.

The committee has not addressed the question of inclusion of proprietary home health agencies beyond the provisions of current law. However, the committee would note that the standards for quality review to be developed should be suitable for application to all home health providers, regardless of sponsorship.

The Secretary of Health, Education and Welfare has been designated to conduct this study in view of the extensive information gathered by the Department during recent regional hearings on home health care and the subsequent activity of the Department in analyz-

ing this information. The Secretary is to include in this report an analysis of the impact of his recommendations on the demand for and cost of services authorized under the programs and the method of financing any recommended increase in the provision of such services.

Uniform Reporting Systems For Health Services Facilities and Organizations (Section 19)

The bill would require the Secretary to establish for each of the different types of health services facilities and organizations a uniform system for the reporting of such items as cost of operation, volume of services, rates, capital assets and bill data. This reporting system would be mandated for use by medicare and medicaid providers and such use would be phased in by type of provider.

A persistent problem under the medicare and medicaid programs as currently structured is the presence of variations in the information contained in medicare and medicaid cost reports. Since it is generally agreed that the existence of comparable cost and related data is essential for effective cost and policy analysis, the assessment of alternative reimbursement mechanisms and, in certain situations, the identification and control of fraud and abuse, the Committee believes it is necessary to correct the deficiencies in the present reporting system under these programs.

Accordingly, the bill requires the Secretary to establish for each type of health service facility or organization a uniform system for the reporting of the following types of informaton:

(1) The aggregate cost of operation and the aggregate volume of services;

(2) The costs and volume of services for various functional accounts and subaccounts;

(3) Rates, by category of patient and class of purchaser;

(4) Capital assets, as defined by the Secretary, including (as appropriate) capital funds, debt service, lease agreements used in lieu of capital funds, and the value of land, facilities, and equipment; and

(5) Discharge and bill data.

It is the committee's intent that the uniform reporting system for each type of health service facility or organization provide for appropriate variation in the application of the system to different classes of facilities or organizations within that type. The Secretary would be required to develop and establish uniform reporting systems, after consultation with interested parties, for hospitals, skilled nursing facilities and intermediate care facilities within a year following enactment of this legislation, and for other types of health service facilities and organizations (such as home health agencies) within two years of enactment.

Within each class of facility, cost allocation formats and definitions should be uniform. Each institution of a particular type performing a function to which a standard applies should be required to report on such functions in the same way. For example, all hospitals should be required to report X-ray costs on the basis of costs per patient exposure to diagnostic X-ray. Another type of institution, such as a long term care facility, may be required to employ another method, if one more suited to such type of institution's operations can be formulated. This

combination of variation by institutional type and uniformity within each such type of institution provides necessary flexibility while assuring that the information obtained is useful.

It is also the committee's intent that the Secretary should take into account the unique organziational arrangement of health maintenance organizations, and should make those adjustments he finds necessary and appropriate to tailor the uniform reporting system to their particular situation, while maintaining the necessary comparability of data.

Under the bill, the Secretary would require all medicare and medicaid providers of services to submit reports to the Secretary of the aforementioned cost-related information in accordance with the uniform reporting system. For hospitals, skilled nursing facilities, and intermediate care facilities, these uniform reports would be required beginning with their first fiscal year that begins more than six months after the reporting system has been promulgated by the Secretary. For all other types of health service facilities or organizations, the reporting requirement will only be implemented at such time (after such systems are promulgated for these institutions) as the Secretary deems to be most productive. After establishing the uniform systems of reporting, the bill requires the Secretary to monitor their operation, assist with support demonstrations and evaluations of the effectivness and cost of the operation of such systems, encourage State adoption of such systems and periodically revise the systems to improve their effectiveness and diminish their cost.

Under the bill, the Secretary would be required to provide such information obtained through use of the uniform reporting system as may be necessary to assist health systems agencies and State health planning and development agencies carrying in out such agencies' functions.

Although this bill does not require uniform accounting as well as uniform reporting, the committee is convinced that the Secretary of HEW should develop model uniform accounting systems and that he should have the authority to require the use of such parts of the accounting system as he finds necessary in the future if his evaluation of uniform reporting indicates that it has not been sufficient to assure reliable and comparable data. The Committee notes that such authority is necessary to implement an effective and equitable hospital cost containment system, since payments based on comparative performances of like hosiptals requires a high degree of comparability of cost data.

Delay in, and Waiver of, Imposition of Reduction of Federal Medical Assistance Percentage Due to a State's Failure to Have an Effective Medicaid Utilization Control Program (Section 20)

Section 20 provides an additional 6-month period to States to meet the requirements of current Medicaid law concerning review of care delivered in institutional facilities. The section provides that if a State is in compliance for the calendar quarter ending December 31, 1977, the Secretary may waive all (or such part as is appropriate) of the reduction in the Federal financial assistance percentage which would otherwise be imposed on those States that failed to fulfill the require-

ments of law during the previous periods. The section further specifies procedural requirements for the Secretary to carry out the validation requirements under Section 1930(g)(2) in more timely fashion. The section defines the conditions a State must meet to be considered in full compliance with the utilization control requirement.

The "Social Security Amendments of 1972" (Public Law 92–603) added section 1903(g) to the Social Security Act. This section requires a one-third reduction in Federal matching payments under medicaid for long-term stays in institutional settings, unless a State demonstrates that it has an adequate program of control over the utilization of institutional services. The program must include a showing that:

(1) The physician certifies at the time of admission and recertifies every 60 days that the patient requires inpatient institutional services.

(2) The services are furnished under a plan established and periodically reviewed by a physician.

(3) The State has a continuous program of utilization review whereby the necessity for admission and continued stay of patients is reviewed by personnel not directly responsible for care of the patient, not financially interested in a similar institution, or, except in the case of a hospital, employed in the institution.

(4) The State has a program of independent medical review for SNF's, ICF's, and mental hospitals whereby the professional management of each case is subject to independent annual review. The section further requires the Secretary to conduct sample on-site surveys of institutions as part of his validation procedures.

The committee notes that this section was to go into effect on July 1, 1973, as an incentive payment for States showing a satisfactory program of utilization control. States which did not make the requisite showings were automatically to be subject to the reduced Federal matching rate. Despite the clear intent of the law and extensive evidence developed by the Subcommittee on Oversight and Investigations as well as the Comptroller General of the United States, that a large number of States failed to meet the requirements, HEW indicated that it was reluctant to impose the reductions. The first reduction actually to be imposed under this authority was announced to take effect July 1977. During the intervening four-year period the committee has on a number of occasions, both during hearings and in a report prepared by the committee, indicated its concern that HEW had failed to fulfill its responsibilities.

On June 8, 1977, HEW announced that it would reduce July 1977 Medicaid payments to 20 States by a total of $142 million (actual application of these announced reductions was delayed by Public Law 95–59 until October 1977). These reductions were to take effect because the States failed, during the first quarter of 1977, to conduct annual medical reviews of patients in long-term care facilities. The Department further announced that it had under review the potential disallowance of $378 million of fiscal year 1975 funds for failure to have adequate utilization controls in place, based upon validation requirements. The committee is encouraged that the Department has begun to aggressively implement the congressional mandate. However, in view of past inaction on the part of HEW, it feels that the sudden reduction in Federal funds for past years activities could have a severe

and unanticipated impact on affected State Medicaid programs. Further, Congress intended this program to be an incentives program to be validated on a current basis by HEW. Section 20 is intended to bring this validation process into timely synchronization with State showings.

The committee has approved an amendment which would give States an additional 6 months to demonstrate full compliance with the law. The committee emphasizes that this is in no way to be viewed as a retrenchment or a lack of resolve on its commitment to effective utilization control and medical audit programs. It fully expects and intends that during this extension period all States will take the necessary actions to bring them into full compliance.

The committee bill amends section 1903(g) to provide that no reduction shall be imposed before January 1, 1978, unless a notice of the decrease is provided to the State at least 30 days in advance and unless notice of the reduction occurs no later than nine months following the period for which the State has been cited for noncompliance.

The Secretary is required to waive application of all or part (as is appropriate) of any decrease otherwise required to be imposed with respect to cases of noncompliance occurring prior to October 1, 1977, if he determines that the State makes a satisfactory showing, and the showing is valid, that it is in full compliance with the law for the last quarter of calendar year 1977. The committee has left to the Secretary's discretion the amount of the decrease which may be waived. It fully expects that where previous violations of the law have been of sufficient magnitude, the Secretary may impose a portion of the penalty. In cases where the State is not able to show a satisfactory program that is validated by the Secretary, the committee expects that all previous reductions will be taken.

The committee bill provides that a State should provide its showing with respect to a calendar quarter to HEW within 30 days of the end of the quarter, so that HEW can make the appropriate determinations and give States sufficient notice of any action (although HEW can extend the period if the Secretary finds good cause for doing so). The section further clarifies the conditions a State must meet to be deemed in full compliance with the on-site medical and independent review requirements. It must demonstrate good faith efforts to conduct on-site surveys in all mental hospitals, SNF's and ICF's and actually conduct such surveys in all large institutions, and in all other institutions in the State. This provision was included because HEW has announced penalties on States which failed to review only two or three homes out of hundreds of homes subject to review within the annual time limit. In the light of the Secretary's position that HEW has no discretion in determining that the requirements of the law have been met, the Committee has provided a standard of reasonableness in the bill.

While existing law requires the Secretary to undertake on-site validation surveys in timely fashion, HEW has not done so in the past. When they have performed validations, the validations have lagged months and even years behind the year in question. The committee believes HEW has an obligation to the States, to the Congress, and to institutional care recipients to undertake validations in a timely fashion, and to impose any reductions resulting from them at that

point. States should not be subjected to the uncertainty of a possible reduction years later. Therefore, the committee reluctantly concludes that HEW should not attempt validations of periods now long past, but should begin now appropriate validations of calendar year 1977, so that they can complete their validations shortly after the December 31, 1977, date for State compliance. The bill requires that the Secretary must complete his validations and give notice of his determinations within nine months of the end of the period in question if he is imposing reductions on the States as a result.

The section also requires the Secretary to submit to the Congress within 60 days of the close of each calendar quarter a report on: (1) his determination as to whether showings made by States are satisfactory; (2) his review of the validity of previously submitted showings; and (3) any reductions made for the quarter.

VI. Congressional Budget Office Cost Estimate

A cost estimate was requested on H.R. 3 when it was ordered reported from the committee on Interstate and Foreign Commerce, and the Congressional Budget Office has provided the following information.

Congressional Budget Office,
Washington, D.C., June 28, 1977.

Hon. Harley O. Staggers,
Chairman, Committee on Interstate and Foreign Commerce, U.S. House of Representatives, Washington, D.C.

Dear Mr. Chairman: Pursuant to section 403 of the Congressional Budget Act of 1974, the Congressional Budget Office has reviewed H.R. 3, the Medicare-Medicaid Fraud and Abuse Amendments, with regard to its potential cost impact.

The provisions in H.R. 3 are intended to clarify and extend current statute in order to facilitate both state and federal efforts to monitor and control possible fraud and abuse in the Medicare and Medicaid programs. This is accomplished in the bill through the expansion both of legislative powers and sanctions and of the collection and coordination of relevant information, as well as through the provision of increased funding to the states to support such activities. Lastly, as a means of further reducing costs, the bill permits the Secretary of HEW to require that necessary durable medical equipment be purchased rather than rented under medicare if it is determined that purchase would be a less costly alternative.

Thus, many of the provisions in this bill represent possible added costs or savings (or both) to the programs. Some sections, for example, although requiring additional expenditures, are intended to actually reduce costs, thus representing no net outlay effect. However, limitations of available and relevant data, uncertainties of the actual extent and effectiveness of the future implementation of the provisions, and the unknown magnitude of the fraud and abuse presently extant in the programs make it impracticable for CBO to project the actual cost impact of this measure at this time.

Our review of the bill and the limited information available leads us to conclude that costs and savings would essentially offset each other during the first couple of years of implementation with some

savings accrued subsequently. This assessment is based upon the fact that the early years would involve both the necessary start-up costs and the time to bring the various activities up to a level where their full cost savings impact would be seen.

If we can be of further assistance to you in this matter, please feel free to contact me.

Sincerely,

ROBERT A. SUNSHINE,
(For Alice M. Ravin, Director).

The committee concurs in the estimate furnished by the Director of the Congressional Budget Office relative to the cost impact of H.R. 3 as amended.

VII. INFLATION IMPACT STATEMENT

The committee anticipates that the enactment of H.R. 3 as amended will slow the inflationary trend experienced by Medicaid and Medicare in recent years by improving the administration and operation of the programs, reducing fraudulent and overstated claims, and reducing abuse of the program.

VIII. OVERSIGHT FINDINGS

The committee's principal oversight activities with respect to this program have been conducted by the Subcommittee on Health and the Environment in connection with its consideration of legislative amendments to deal with fraud and abuse in the program, and by the Subcommittee on Oversight and Investigations. Legislative hearings on fraud and abuse in medicaid were conducted in September of 1976 and March of 1977. The findings are discussed under the background of the bill and the committee proposal, as the proposed legislation is designed to respond to the subcommittee's findings. Oversight hearings on problems of abuse, fraud, utilization control programs, and related issues in medical care programs were conducted by the Subcommittee on Oversight and Investigations in 1975, 1976, and 1977. The following reports were issued: Getting Ready for National Health Insurance: Unnecessary Surgery; Cost and Quality of Health Care: Unnecessary Surgery; Oversight HEW Activities; Problems of Medicaid Fraud and Abuse: Public Protection Activities of HEW; and Nursing Home Abuses. Information contained in these reports was used in the development of the proposed legislation.

Additionally, the findings of the Subcommittees on Health and Oversight of the Ways and Means Committee, of the Senate Committee on Aging, and of the Permanent Investigations Subcommittee of the Senate Government Affairs Committee have been available to the committee and of value to them in the legislative considerations.

The committee has not received oversight findings with respect to this subject from the Committee on Government Operations.

IX. APPENDIX

I. Letter from the Secretary of HEW to the Chairman of the Subcommittee on Health and the Environment, Committee on Interstate and Foreign Commerce.

II. Letter from the Assistant Director of the Office of Management and Budget.
III. Excerpt Transcript of Testimony by Witnesses from the Administration Concerning the Impact of the Amendment Adopted by the Ways and Means Committee.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
June 8, 1977.

Hon. PAUL G. ROGERS,
Chairman, Subcommittee on Health and the Environment, Committee on Interstate and Foreign Commerce, House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: I wish to advise you of our grave concern over last week's Ways and Means Committee amendment on H.R. 3 which sharply restricts the access of Federal officials to individually identifiable medical records.

An immediate consequence would be to hinder many of our efforts to protect the public heatlh. Monitoring the health of the nation through surveys on the incidence of disease and through studies on the outcome of disease and therapies would be greatly hampered by the proposed legislation, as would the Department's capabilities for responding to real or threatened epidemics. It would also seriously impair our studies of the origins of disease, particularly those resulting from environmental hazards that may take decades before symptoms are noted.

The reasons why the Department cannot carry out its responsibilities for public health and medical science under the proposed restriction of access to instances in which the subject has given prior consent to the use of its medical record are:

1. In an impending epidemic situation where PHS investigators have been called in to help control or prevent the epidemic, they must have swift and unimpeded access to any and all medical records of the community, often going back over a period of several years. Local resources can be quickly overwhelmed, and CDC investigative teams are often called upon in emergencies. They could not help protect the nation's health under the proposed legisaltion.

2. Obtaining the patient's consent to use his medical record is impractical when large numbers of identifiable records created years ago must be screened to select subjects, and controls, for follow-up. Many patients cannot be found, others are deceased, and next of kin are unavailable.

3. By allowing a potential subject of an epidemiologic study to decide whether he will be studied the investigator would often lose the very basis for drawing inferences from his study—the representativeness of his cases and controls. In the DES study preliminary data suggest that "walk-ins" who volunteer themselves for study have twice the prevalence of the abnormalities suffered by the representative subjects. Such bias can go either way.

4. To require the patient's informed consent at the time the medical record is created would limit all investigation to studies under way and to the limited state of medical knowledge of that time. The record

could not be used in any future study of a new problem without encountering the problems of item 2 above.

5. In the incidence surveys, e.g., the recent Third National Cancer Survey and the current neurologic disease surveys, *all* known or suspected cases of the disease in question must be reviewed for duplication and for validity if true incidence is to be learned. If the subjects of the survey were free to decide whether or not to be counted in the survey, it would cease to have any public health value.

Here are examples of well known work which could not have been done under the restriction now in the Ways and Means version of H.R. 3:

CONTROL OF EPIDEMIC

The investigation of the Legionnaires' disease in Philadelphia in the summer of 1976 required the swift review of hundreds of charts from five city hospitals to determine if the disease had spread beyond the focus of the Belleview Stratford Hotel to the rest of Philadelphia.

In 1955, an outbreak of Poliomyelitis among 100 children required a full investigation of hundreds of cases to identify a contaminated lot of vaccine. Stopping the use of the vaccine prevented the occurrence of more cases.

Coping with the 1971 Southern Texas epidemic of Venezuelan equine encephalitis transmitted from infected horses to humans via the mosquito required review of hospital records in 38 Texas cities. Daily review of all hospital records by Federal and State medical epidemiologists was required as part of the successful effort to contain the disease.

CONTROL OF CHRONIC DISEASE

Some important medical advances have required the examination of records of medical practices of many years ago to trace subsequent specific effects on certain persons or their offspring. For example, the discovery of the danger of vaginal cancer in the children of women treated with DES 20 years ago required examination of records decades old as well as current records. In studies of this nature, the notion of informed consent is frequently meaningless.

Whether routine mammography of women under age 50 is a beneficial public health measure to control breast cancer is now of great concern. Our only present information on the risk of breast cancer from ionizing radiation derives from studies of the A-bomb survivors in Japan, former tuberculosis patients who routinely received fluoroscopy to monitor pneumothorax therapy, and patients with mastitis treated by X-ray. All these studies have required access to individually identified records even to define the set of women, and suitable control subjects, to be studied. Valid studies cannot be done if the patient's consent must be obtained before records are examined.

The cancer maps recently prepared by investigators in the National Cancer Institute have thrown the spotlight on a number of counties with very high death rates from specific forms of cancer. To learn why the rates are so high, and to provide the basis for control measures, investigators must now examine the medical records of each such county over a period of some years, selecting cases of cancer, and suitable control subjects, for more specific study by means of inter-

views of surviving subjects or the next of kin of the deceased. The subjects for study cannot be known without first examining the medical records with all their individual identifiers, and the identifying information must be retained throughout the follow-up process. Once all the information on a person has been assembled, however, a case number will suffice for identification and statistical processing. The individual again becomes anonymous.

The estrogens have been widely employed in preventive and therapeutic medicine in birth control, in preventing spontaneous abortion, in the management of menopausal and post-menopausal symptoms, and even in the treatment of advanced breast cancer. But we are learning that the estrogens also carry risks, especially of cancer, and it is vital that we determine how great these risks are. The problem requires research over the long term, going back decades in some instances to the subjects, and controls, for follow-up. Again, consent cannot be sought until the investigator has reviewed the potentially eligible records and selected representative women for study.

The objective of the amendment—i.e., the protection of individually identifiable medical records from improper disclosure—is one we wholly endorse. Indeed, I affirm our commitment to comprehensive review of the entire issue of medical records and confidentiality.

The Privacy Protection Study Commission has been at work two years and has carefully considered the need for proper access to ensure the protection of the public health and the need for regulations to protect the privacy of the individual. We believe both issues must be considered comprehensively.

Therefore, we support the language adopted by your Subcommittee requiring the Department to deliver to the Congress within 90 days after the release of the Privacy Commission's Report our plan, including whatever draft legislation may be required, to implement the Commission's recommendations on medical records. We would appreciate your support in averting an overeager measure the purpose of which is commendable but whose unintended consequences would impose costs to our pursuit of health goals that would outweigh the benefit to patient privacy.

Sincerely,

JOSEPH A. CALIFANO, JR.

EXECUTIVE OFFICE OF THE PRESIDENT,
OFFICE OF MANAGEMENT AND BUDGET,
Washington, D.C., June 13, 1977.

Hon. PAUL G. ROGERS,
Chairman, Subcommittee on Health and the Environment, Interstate and Foreign Commerce Committee, House of Representatives, Washington, D.C.

DEAR CHAIRMAN ROGERS: I would like to express our deep concern over an amendment to H.R. 3 recently introduced by Mr. Crane which would prohibit the Federal Government or its agents from inspecting, acquiring or requiring the disclosure of any part of an individually identifiable medical record without first having obtained consent from the individual(s). While we understand that a recent and serious in-

vasion of privacy related to a Federally funded project was a precipitating factor in the re-introduction of this amendment, we believe, for a number of reasons, that the amendment is not in the best interests of the public.

We believe that a significant amount of medical and epidemiologic research which is designed to increase knowledge of disease etiology, forecast and control epidemics, and in general, protect the health of the public, and which would be seriously curtailed by adoption of the amendment, should continue.

In addition, the ability to assess progress of several of the President's initiatives would be hampered by adoption of the amendment. For example, in his May 23 message to the Congress on environmental issues, the President committed the Administration to protecting human health from environmental hazards. To assess short and long-term effects of protection programs on health status, large-scale, rigorous epidemiologic studies which rely on examination of medical records may need to be undertaken, but would be inhibited by the amendment's adoption. Another example of the damaging effect of adoption of the amendment on the ability to assess progress on a Presidential initiative is in the area of health care cost containment. The acquisition and examination of hospital discharge data from medical records is essential to determine the extent of such progress and is most necessary given the importance of escalation of hospital care costs as a component of overall health care cost escalation.

The Department of Health, Education, and Welfare has clearly cited reasons why obtaining prior consent from individuals to examine medical records is, in a great many instances and for a great many purposes, including those noted above and others which we have not mentioned, not practicable.

Many Federal agencies are involved in the conduct of medical and epidemiologic research which requires examination of medical records, and these agencies rely on each other's results and experiences to further their own guest for knowledge in these areas. Although agency medical and epidemiologic research may appear fragmented and uncoordinated, in fact there is a great deal of interdependency and coordination between agencies resulting in a systematic Federal research program. Consequently, exempting any single agency or group of agencies from the amendment's requirements would not be sufficiently ameliorative.

While we understand the grave concerns relating to the protection of privacy which the Congress has, and which are shared by this Administration, we believe that it would be premature to adopt this or related amendments prior to considering the soon-to-be released recommendations from the Privacy Protection Study Commission.

Once such recommendations are presented, and individual agencies have had an opportunity to develop positions on modifying their research and data collection activities based upon such recommendations, the Executive Branch will propose comprehensive guidelines, regulations and legislation to further insure that the privacy of individuals is protected.

Sincerely,

James M. Frey,
Assistant Director for Legislative Reference.

Excerpts of Transcript of Testimony Before the Subcommittee on Health and the Environment, June 13, 1977

[The Subcommittee on Health and the Environment met to reopen their consideration of H.R. 3 and to take testimony on the amendment concerning confidentiality of medical records adopted by the Ways and Means Committee. Witnesses that appeared as a panel before the subcommittee included Mr. Grant Spaeth, Deputy Assistant Secretary for Health Legislation, HEW; Dr. William Foege, Director of the Center for Disease Control, HEW; Dr. Robert Gordon, National Institutes of Health, HEW; Dr. Marvin Schneiderman, National Cancer Institute, HEW; Lt. Colonel N. Bruce Chase of the Health Council Secretariat, Department of Defense; Ms. JoAnne Langston, Associate Executive Director, U.S. Consumer Product Safety Commission; Dr. August Vandermer of the Environmental Protection Agency, and Mr. Frederick W. Kutz of EPA. Excerpts of their presentations before the subcommittee follow:]

Dr. GORDON. Perhaps I could start. Our real concern is that when an excessive care for the protection of privacy of an individual subject goes to an extreme, one sacrifices the societal need for information about the causation of the prevention of disease.

Thus, people who are not a part of this individual medical record would have to pay, we feel pay too heavily, for the absolute protection of privacy. There is a need to find a way so that privacy can be protected or, if need exists for information, that information can be so safeguarded that it is made known to no one except the investigators who are working in the public interest.

All through the last 2 years, the Privacy Protection Study Commission has been working very hard with the help, of course, of not only this Department but many others, to try to find the best compromise between the problems that we know exist, if private information is made available to private investigators, and, on the other side, of the inability of our research and statistical programs primarily to protect the public health if they are denied access to records.

Our concern with this proposed amendment is that it goes too far in the direction of protecting the individual and sacrifices other interests. We are prepared to bring up any number of discrete examples to try to make this clear. I think the discrete examples will be perhaps much more interesting than generalizations.

* * * * * * *

Dr. FOEGE.

There are two areas with which we are concerned. The first would be epidemic investigations. As an example, last December when we had the first suggestion that Gullain-Barre syndrome may be related to influenza vaccine, it was necessary quickly to identify cases by looking at hospital records, doctors' records and with an individual then going to the patient to find out if they had received vaccine or had not received vaccine.

It was possible within one week to make some suggested relationship between Gullain-Barre and flu vaccine.

The new penicillin destroying gonococcus strain is another example. The surveillance system picks up this organism in the lab, links that finding to an individual, allows investigators to go to that individual and get names of other contacts, in order that the entire epidemic can be treated and the transmission of this particular organism can be interrupted.

In 1975, the St. Louis encephilitis broke out in Illinois. It was necessary to review quickly 2,000 hospital records to determine which geographic areas were involved with this outbreak so that mosquito programs could be aimed specifically at target areas.

In 1976 with the Legionnaires' disease in Philadelphia, it was necessary to review quickly hospital records to find other previously unknown cases of Legionnaires' disease, but also in other areas of Pennsylvania to discover was there secondary spread from these initial cases to family members or to other people in the community.

Another area of concern is with our ongoing disease control work. For instance, with the vaccine-preventable diseases it is necessary to look at records to find susceptible children, children who have no records of previously receiving immunizations, or no records of previously having the disease to target immunizations to those particular children.

It is also necessary, if one is to discover other vaccine complications, to go to hospital records, find the suspected complication and then go back to the individual to find out if they received vaccine and temporally how that is associated to the complication.

The problem of venereal disease goes beyond the penicillinase-producing strain. Every day literally hundreds of people are interviewed in this country because venereal disease has been picked up in a lab and related to an individual who is then questioned. I might mention that in the last 18 months, for the first time in a long time, we seem to be stemming the tide of venereal disease, and it is very important to continue this kind of work.

These are some very quick examples, but I think, from our point of view, it would compromise the control and the prevention of both communicable and noncommunicable diseases, if we were unable to link records with individual patients for followup.

Mr. Spaeth. Of the parts of the National Institute, probably the one most dramatically impacted by this legislation is the work to find the cause and prevention of cancer. For that reason, we have asked Dr. Schneiderman, the Associate Director of Epidemiology, to share with you some of the problems we foresee in the war on cancer, if this sort of language were enacted.

Dr. Schneiderman. I see four things that we do which require our knowing with whom we are doing it, the people who are involved. The first is the follow-up, the kind of thing

that the gentleman from New Jersey and other States are acquainted with, with the help of Mrs. Rice and her group at the National Health Center for Health Statistics.

We were able to put together statistics on cancer mortality, county by county in this country over a period of twenty years. We found out that there were places where the rates were high.

We now want to find out why these rates are high. Where we can go back into those areas, find the death certificates, find out who these people were who have died of the disease and go back and try to find, did they have concomitant diseases, did they have other diseases, what did they work at, things of that sort.

That is the first step. The second step is to ask this question. Suppose we see, in southern New Jersey, large chemical concentrations, high rates of disease in this particular area. Is this continuing?

Those are mortality data. Is this going on still now?

We then want to look into people who have developed the disease more recently. Are these still people who are working at the same industries or are these people who are now developing the disease for other reasons?

For this reason we want to go back into these particular areas, contact the local hospitals, get the records, find out who these people are, find out where they were and what is going on with them.

The second thing we want to do, we are very concerned with whether cancer is increasing or not increasing, not only in the mortality from the disease, but also whether the disease itself is increasing, whether we have many more cases and if we have many more cases, why are these coming about.

When we look at hospital records and we find that this is John J. McGee who was born on March 17, 1919, we want to make certain we do not report Mr. McGee three or four times. If we report Mr. McGee three or four times, we will have the appearance of a large increase, perhaps, and there is no increase at all.

The first stage is that we have to identify the specific individual and know enough about him to compare records. People who have cancer are not seen by one doctor, one hospital, one specialist.

So those are two of the things.

Third, we want to know if our treatment has been successful, if our research and treatment has been effective. We know in the highly specialized centers we can do very well and in certain forms of the disease we are doing extremely well in treating it. Is this happening in the rest of the country? Is information getting out to physicians in the rest of the country?

Perhaps you know that we followed up on all of the cases of acute leukemia in children who were treated in certain areas of the United States. We had to identify these children

through the hospital records, find out how they were treated, then follow them to see how long these children survived.

There is a great pleasure for us to see that these children had done almost as well as the children in the fine research centers, so this information was getting out into the country, was getting out into the community, and therefore, as far as we were concerned, this technology transfer was really taking place.

Finally, the last thing that we do with these records is one which I think is the most personal aspect of it and affects people most personally. We have begun to note that there are other diseases, other disease complexes, that are then associated with an increase in cancer per se. Some of the things that we found in some children's cancer, a tumor of the kidney, the secondmost children's cancer, which is associated with a very peculiar congenital malformation. Half of the body gets larger than the other half, for some reason or other, not necessarily in this child, but in other members of the family. A particular case was discovered where the mother had it. The child, the tumor.

What we then had to do was follow up and see if we could find the other members of the family, all the other people linked genetically, get them in for medical examinations, see that they get looked at quickly, see that they get followed closely, see that they get appropriate treatment as soon as the disease is picked up.

We discovered a familiar mylonoma syndrome in just this way. Now, going to members of that particular family, we found in about 40–50 members of the family eight mylonomas very early that could be treated because we identified another illness in that family, and clearly you cannot identify families unless we know specifically who the people are.

These are some of the things that we have been doing recently that require our knowing specific information about specific individuals.

For the large-scale epidemiological things, once you get the specific information, you make sure Mr. McGee is not reported more often than once and Mr. McGee that you are following through a survival is the same Mr. McGee. On centralized records, the records we keep in Bethesda, we really no longer have to have Mr. McGee, but we really needed his name to start.

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Colonel CHASE. I am Lieutenant Colonel N. Bruce Chase, Medical Corps, U.S. Army. I am the Medical Plans and Policies Officer for the Department of Defense Health Council Secretariat in the Office of the Assistant Secretary of Defense for Health Affairs. The Department of Defense appreciates this opportunity to comment on the proposed amendment.

We regret that General Baker is ill and could not be here as planned.

In reviewing the proposed amendment to H.R. 3, entitled "Disclosure of individually identifiable medical records," we find that implementation of its provisions could have an extremely serious effect on delivery of health care, on the training of medical personnel, on medical research to improve the prevention and treatment of disease and on other medical programs which are critical to protecting the individual and collective health of our citizens and our military personnel.

It is our opinion that a literal interpretation of the proposed amendment could have the following effect:

Access to a patient's record by his own physician would be restricted;

Access by the nurse and others responsible for implementing the physician's orders would be limited;

Access by clerical personnel who enter laboratory results, electrocardiograms, X-ray reports and other such information would be curtailed;

Access to records by certifying bodies, such as the Joint Committee on Accreditation of Hospitals, for the purpose of determining quality of care, would be restricted;

The normal procedures used in the teaching and training of medical students, interns, residents and other medical personnel would be seriously impaired, particularly in regard to sponsored programs in civilian institutions;

Consultation by the attending physician with other physicians on interpretation of X-rays, electrocardiograms and other such portions of records would be difficult and sometimes impossible;

All medical research studies of a retrospective nature would be very difficult to conduct and under the best of circumstances would suffer substantially in scientific validity. For example, surveys to determine the most effective forms of treatment for cancer, heart disease, stroke and all other diseases would be incomplete at best since it would not be possible to obtain authorization from all such patients involved;

Many prospective medical research studies would have to be abandoned or would be of lower scientific quality than otherwise would exist;

Access to records even for the purpose of extracting coded information would become a cumbersome and inefficient process at best;

Epidemiological information absolutely critical to the swift and effective detection and management of acute epidemic disease in both military and civilian populations would not be available;

Accurate health statistics of any kind could not be assembled;

Detection of occupational diseases would be impaired;

Internal utilization review and quality assurance would be difficult or impossible.

Information on epidemic disease would not be available, information which is absolutely critical to the detection and the management of these diseases. These range from venereal disease to tuberculosis, smallpox and other such diseases. We would not be able to assemble accurate health statistics of any kind, regarding length of stay, casualty rates, disease incidence, and so forth, among our troops.

We would also be unable to perform proper internal utilization of quality assurance unless we have access to all of the records.

We would say that while it would be possible to obtain the patient's authorization to gain access in some of the above situations, it would be at best a very cumbersome system which would consume great amounts of manpower and other resources. In other circumstances, access would not be available at all because of the lack of authority or third party authorization or if people wanted to deny access.

Under these conditions, we think our medical care, our training programs, our research and so forth would all suffer irreparable damage.

Ms. Langston. I am the Associate Executive Director for Hazard Identification and Analysis of the U.S. Consumer Product Safety Commission. The agency has the mandate to protect consumers against unreasonable risk of hazards that are associated with, or caused by, consumer products in order to adequately identify which problems are causing which problems, and then for the Commission to remedy these injuries, we have devised a surveillance system which gathers information from 119 hospitals across the country.

Historically we have been very concerned about the question of privacy and all of the activities that the agency carries out regarding our surveillance system and our subsequent in-depth analyses has, a complete background, the concern for the privacy of the individual.

However, it is imperative that either an employee of the hospital or a contract employee who may come from the State health department or county health department, one of our employees or a contractor have access to the records from the emergency room which describe the product that was associated with the injury which was being treated at that emergency room.

For some fraction of those injuries which are treated in the emergency room, our investigators, the agency investigators go out and do an in-depth investigation. This means that the investigators call the hospital and ask for the name and the address and the phone number of that sample of patients, then call the patient and say, may we come and talk to you and look at the product and see, find out about the accident. We get permission from the patient, but we get permission from the patient after we have the patient's name, which is received from the hospital.

All of the information that is coded by the hospital employees and transmitted to us in Washington every day from

these 119 hospitals does not have any indication of patient name or address. It only has a code number that is known to the hospital, so we go back to the hospital, ask for the identifier, or sample of patients, and call the patient to get the information.

However, the work of the agency would be practically halted if we were not able to get this kind of information about an association of product and injury.

Therefore, it is enormously important that we, for the consumers, are allowed access to this information, recognizing that we do everything possible to protect the identification and to maintain confidentiality and privacy of all of the records.

Dr. VANDERMER. I am Dr. Vandermer with the Human Effects Monitoring Branch Office of Pesticides, EPA. Under the Federal Pesticides and Fungicide Act, we are required to provide some assurances to the public that they are safe from exposure to pesticide chemicals.

We operate several programs within our branch. One of them is the pesticide incident monitoring system in which we respond to pesticide incidents where there has been serious human exposure, essentially any exposure to plants, animals and humans, but of course, those involving humans are more immediately of our concern and especially if it involves people who are, in fact, in a hospital and the physician is needing some recommendation or consultation from the physicans through contract work with our program.

We have developed treatment procedures for some of the more exotic pesticides that are available commonly and we have published a book on this work, a small book which is available. We feel that the amendment to this legislation could interfere with the successful implementation of this kind of activity.

We are also concerned about the possibilities of medical consultation, consultation of other experts in the field and we, in turn, are burdened with the responsibility of making recommendations to the Director of the Office of Pesticides regarding these kinds of threats that can arise in this situation.

Another program that we recently implemented and completed was a study of the instances of hospitalized pesticide poisonings occurring in the nation. This was the first time that anyone had ever done an account of this sort of thing across the nation and the first statistics, which accurately represented the numbers of pesticides poisonings occurring, or being admitted to hospitals, in the country.

To accomplish this study, we randomly selected 700-plus hosiptals from the 7,000-plus general care hospitals in the nation and we abstracted from the medical records of those hosiptals the pesticide poisoning cases and, in turn, were able to extrapolate to the numbers of those in the country. I am not saying that this legislation would make that kind of activity impossible, but it would make it somewhat improbable

that we would be able to implement this kind of activity, certainly at the cost which we did, which was rather small, and it would really impose some tremendous burdens.

I am not sure, but I would have to talk to the statisticians as to how you would go about randomly selecting and then going back to accomplish this kind of activity, without initial access to records.

We also carry on chronic effects studies of persons who have come to our attention who have been acutely exposed to certain kinds of pesticidal chemicals, and we have prospective studies to determine whether or not they are going to experience ongoing kinds of health effects and again, this piece of legislation might interfere with that activity.

Mr. KUTZ. My name is F. W. Kutz, I am the Branch Chief of the Ecological Monitoring Branch in EPA.

We run a program to determine the body burdens and exposures of the general population in the United States to selected chemicals, most of them registered pesticides with EPA

Our program operates on a national basis and does collect a certain amount of limited medical information. We have reviewed the proposed amendment that is under consideration today and find that it would cause a great burden on our program if that were enacted.

Most of our studies are of the epidemiological nature and is is necessary for us to know certain medical and demographic information which is acquired through examination of medical records for us to associate body burdens of pollutants with their human health impact.

I brought a couple of examples along that I would like to show you. We recently concluded a study of the level of polychlorinated biphenals, know as PCB's. In the United States, we find that almost half of the population have levels of PCB's in their body tissues of some kind or another and we have been examining them under the context of determining whether or not we can find any health impact, or cancer, if you will, any relationship with the diagnostic tools that the physicians have given us.

Another impact of this would be our inability to evaluate how our regulatory programs were impacting upon the general population. For example, we have recently concluded a study that shows that the levels of DDT in humans is declining and the most drastic decline is in the younger age group. We would not be able to make that statement unless we knew the ages and some of the medical conditions of the people.

Another study that is underway right now is one that involves myrex. That is a chemical that is used for imported fire control in the Southeastern part of the United States. We find that myrex in laboratory animals produces a pattern of carcinomas or malignant tumors of the liver.

We find that this is a chemical that is capable of being stored in fat tissue of the human body. We are now evaluating that in the southern part of the United States.

These are just a few of the examples. Another one you might be interested in: we find these pesticides and PCB's are racially stratified in that, for example, in the storage of TGB and in the storage of PCB's, our specimens from blacks seem to contain twice the amount of DDT and polychlorinated biphenyls as those samples do from Caucasians.

These are just a few examples of how we use medical information.

A recent release from the Council on Environmental Quality indicates that 80 to 90 percent of cancer is caused by environmental factors. I believe we have a responsibility to investigate these factors. I think the amendment that you are considering now would cause us a heavy burden, if we do.

I also believe that it would be remiss of me not to point out that there are presently a number of various laws that do impact on the privacy and confidentiality of medical information. The present HEW policy on protection of human health volunteers is followed, in all cases, by our research. The Freedom of Information Act contains exemptions for medical information. Also, the Privacy Act has an impact one this.

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X. Section-by-Section Analysis

The section-by-section analysis contained in Part I of the report reflects the amendments reported by the Committee, with the exception of the following:

Section 5(2)(1) amends Section 1166 of the Social Security Act by adding a new subsection which provides that no officer, employee or agent of a Professional Standards Review Organization may disclose to any officer, employee or agent of the Federal Government (and no officer, employee or agent of the Federal Government may have access to or inspect) any individual identifiable medical record in the possession of the Professional Standards Review Organization which relates to medical care not provided or paid for (in whole or in part) by the Federal Government or through a program receiving Federal financial assistance unless the patient has properly authorized such disclosure.

A patient authorizes disclosure and inspection of an individually identifiable medical record only if, in a signed and dated statement, he—

(1) Authorizes the disclosure and inspection for a specific period of time;

(2) Identifies the medical records authorized to be inspected or disclosed;

(3) Specifies the purposes for which the record may be inspected or disclosed; and

(4) Specifies the agencies which may inspect the record or to which the record may be disclosed.

For purposes of this section, the term "individually identifiable medical record" means a medical, psychiatric or dental record concerning an individual that is in a form which identifies (or permits identification of) the individual through means available to the public.

Section 5(l)(2) requires the Secretary, after taking into consideration the recommendations contained in the final report of the Privacy Protection Study Commission (established under section 5 of the Privacy Act of 1974), to prepare and submit a report not later than three months after the date such Commission submits its final report. The report shall be submitted to the Committee on Interstate and Foreign Commerce and the Committee on Ways and Means of the House of Representatives and to the Committee on Human Resources and the Committee on Finance of the Senate. The report shall contain specific recommendations (including draft legislation) for the timely development and implementation of appropriate procedures (including use of detailed written consent forms) in order to: (1) maintain the confidentiality of individually identifiable medical records (whether they relate to medical care provided directly by, or through the financial assistance of, the Federal Government or not), and (2) prevent the unwarranted inspection by, and disclosure to, Federal officers, employees, and agents and PSRO's of such records.

Section 17(a) amends section 1903(a) of the Social Security Act by redesignating section 1903(a)(7) as section 1903(a)(8) and inserting a new section 1903(a)(7). New section 1903(a)(7) would provide Federal matching assistance to each State with an approved State plan for medical assistance in order to establish and operate a State medicaid fraud control unit (including assistance to train personnel employed by such units). The Secretary would be required to pay each State an amount equal to 90 percent of the costs incurred during a quarter beginning on or before October 1, 1977, and ending before October 1, 1980, to establish and operate these units (as defined in new section 1903(p)), if he finds that such assistance is necessary to eliminate fraud in the provision and administration of the State's medicaid program.

Section 17(b) amends section 1903(b) of the Social Security Act by adding a new section 1903(b)(3). New section 1903(b)(3) specifies that the amount of funds which the Secretary must pay a State during a quarter under new section 1903(a)(7), cannot exceed the higher of:

(a) $125,000, or

(b) one-quarter of 1 percent of the sums spent by the Federal, State, and local governments during the previous quarter in carrying out the State's plan for medical assistance under title XIX of the Social Security Act.

Section 17(c) amends section 1903 of the Social Security Act by adding a new section 1903(p). New section 1903(p) defines the term "State medicaid fraud control unit" (for the purposes of section 1903) to mean a single identifiable entity of the State government which the Secretary certifies (and annually recertifies) as meeting the following requirements:

(1) The entity (A) is a unit of the office of the State Attorney General or of another department of State government which possesses statewide authority to prosecute individuals for criminal violations, or, (B) if the entity is located in a State where the State constitution does not provide for the prosecution of individuals by a Statewide authority, has formal procedures ap-

proved by the Secretary which assure referral of suspected criminal violations relating to Medicaid to the appropriate authority, and which assure the assistance of the authority in the prosecutions.

(2) The entity is separate and distinct from the single State agency that administers or supervises the administration of the State plan for medical assistance under title XIX of the Social Security Act.

(3) The entity's function is conducting a statewide program to investigate and prosecute violations of all applicable State laws regarding any and all aspects of fraud in connection with any aspect of the provision of medical assistance and the activities of providers of such assistance under the State plan for medical assistance under title XIX of the Social Security Act.

(4) The entity has procedures to review complaints of the abuse and neglect of patients in health care facilities which receive payments under the State plan for medical assistance approved under title XIX, and, where appropriate, of the Social Security Act to act upon these complaints under the criminal laws of the State or refer them to other State agencies for action.

(5) The entity provides for the collection, or referral for collection to a single State agency, of overpayments made under the State plan for medical assistance to health care facilities which are discovered by the entity in carrying out its activities.

(6) The entity employs such auditors, attorneys, investigators, and other necessary personnel and is organized in such a manner as is necessary to promote the effective and efficient conduct of the entity's activities.

(7) The entity submits to the Secretary an application and annual reports containing such information as the Secretary determines, by regulation, to be necessary to determine whether the entity meets the other requirements of new section 1903(p).

Section 17(d)(1) specifies that the amendments made section 17(a) apply only to calendar quarters beginning after September 30, 1977.

Section 17(d)(2) requires the Secretary of HEW to establish regulations to carry out the amendments made under section 17 within 90 days after this legislation is enacted.

Section 20(a) amends section 1903(g) of the Social Security Act by inserting a requirement that sample onsite surveys be timely, and by adding a new paragraph (3). New section 1903(g)(3) provides that no decrease in the Federal medical assistance percentage of a State otherwise required by the provisions of subsection (g) shall take effect before January 1, 1978. It further requires the Secretary to provide a notice of the decrease to the State at least 30 days before the decrease takes effect. Additionally, it provides that no decrease which results due to the State's unsatisfactory or invalid showing made with respect to a calendar quarter beginning after September 30, 1977, can take effect unless notice of such decrease has been provided to the State by the first day of the fourth calendar quarter following the calendar quarter in question.

The subsection provides that the Secretary shall waive all (of such part as is appropriate) of any decrease in Federal matching payments

otherwise required for quarters ending before October 1, 1977, if the Secretary finds that a State's showing made with respect to the calendar quarter ending on December 31, 1977, is satisfactory.

The subsection provides that no showing of a State may be found satisfactory unless it is provided to the Secretary no later than the 30th day after the last day of the calendar quarter with respect to which it is submitted (unless the Secretary finds good cause for the State not meeting the deadline). In addition, if the showing demonstrates that the State has conducted on-site inspections during the 12-month period ending on the last date of the calendar quarter in each of the mental hospitals, skilled nursing facilities and intermediate care facilities of 200 or more beds, and at least 98 percent of all other such facilities, and that the State has made a good faith attempt with due diligence to review all such facilities subject to the review provisions of the law, the Secretary will find the showing to meet the onsite inspection requirement.

The subsection further requires the Secretary to report to the Congress no later than 60 days after the end of each calendar quarter on his determination of whether a State's showing is satisfactory, his review through onsite surveys and other methods of the validity of the showings previously submitted by a State, and any reductions he has imposed on a State because of the provisions of section 1903(g).

Section 20(b) provides that the amendments made by subsection (a) shall become effective on June 30, 1977, and that the Secretary of HEW shall promptly make any adjustment of payments made to States which are necessary to reflect the changes made by the amendment.

XI. Changes in Existing Law Made by the Bill, as Reported

In compliance with clause 3 of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported are shown below using the following typographical devices (with "W & M" referring to the Committee on Ways and Means and and "IFC" referring to the Committee on Interstate and Foreign Commerce):

Existing Law—

—in which no change is proposed by W & M or IFC, printed in roman.

—proposed to be omitted by both W & M and IFC, enclosed in black brackets, viz., [ ].

—proposed to be omitted only by IFC (and not by W & M), printed in ~~linetype.~~

New Matter—

—proposed to be inserted by both W & M and IFC, printed in *italic.*

—proposed to be inserted only by W & M (and not by IFC), printed in ~~*italic linetype.*~~

—proposed to be inserted only by IFC (and not by W & M), printed in **boldface roman.**

TITLE XI—GENERAL PROVISIONS AND PROFESSIONAL STANDARDS REVIEW

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Part A—General Provisions

DEFINITIONS

Sec. 1101. (a) When used in this Act—

(1) The term "State", except where otherwise provided, includes the District of Columbia and the Commonwealth of Puerto Rico, and when used in titles IV, V, VII, XI, and XIX includes the Virgin Islands and Guam. Such term when used in title V *and in part B of this title* also includes American Samoa and the Trust Territory of the Pacific Islands. Such term when used in titles III, IX, and XII also includes the Virign Islands. In the case of Puerto Rico, the Virgin Islands, and Guam, title I, X, and XIV, and title XVI, (as in effect without regard to the amendment made by section 301 of the Social Security Amendments of 1972) shall continue to apply, and the term "States" when used in such titles (but not in title XVI as in effect pursuant to such amendment after December 31, 1973) includes Puerto Rico, the Virgin Islands, and Guam.

* * * * * * *

(9) The term "shared health facility" means any arrangement whereby—

(A) two or more health care practitioners practice their professions at a common physical location;

(B) such practitioners share (i) common waiting areas, examining rooms, treatment rooms, or other space, (ii) the services of supporting staff, or (iii) equipment;

(C) such practitioners have a person (who may himself be a practitioner)—

(i) who is in charge of, controls, manages, or supervises substantial aspects of the arrangement or operation for the delivery of health or medical services at such common physical location, other than the direct furnishing of professional health care services by the practitioners to their patients; or

(ii) who makes available to such practitioners the services of supporting staff who are not employees of such practitioners; and

who is compensated in whole or in part, for the use of such common physical location or support services pertaining thereto, on a basis related to amounts charged or collected for the services rendered or ordered at such location or on any basis clearly unrelated to the value of the services provided by the person; and

(D) at least one of such practitioners received payments on a fee-for-service basis under titles V, XVIII, and XIX in an amount exceeding $5,000 for any one month during the preceding

12 months, or in an aggregate amount exceeding $40,000 during the preceding 12 months;

except that such term does not include a provider of services (as defined in section 1861(u) of this Act), a health maintenance organization (as defined in section 1301 of the Public Health Services Act), a hospital cooperative shared services organization meeting the requirements of section 501(e) of the Internal Revenue Code of 1954, or any public entity.

* * * * * * *

UNIFORM REPORTING SYSTEMS FOR HEALTH SERVICES FACILITIES AND ORGANIZATIONS

SEC. 1121. (a) For the purposes of reporting the cost of services provided by, of planning, and of measuring and comparing the efficiency of and effective use of services in, hospitals, skilled nursing facilities, intermediate care facilities, home health agencies, health maintenance organizations, and other types of health services facilities and organizations to which payment may be made under this Act, the Secretary shall establish by regulation, for each such type of health services facility or organization, a uniform system for the reporting by a facility or organization of that type of the following information:

(1) The aggregate cost of operation and the aggregate volume of services.

(2) The costs and volume of services for various functional accounts and subaccounts.

(3) Rates, by category of patient and class of purchaser.

(4) Capital assets, as defined by the Secretary, including (as appropriate) capital funds, debt service, lease agreements used in lieu of capital funds, and the value of land, facilities, and equipment.

(5) Discharge and bill data.

The uniform reporting system for a type of health services facility or organization shall provide for appropriate variation in the application of the system to different classes of facilities or organizations within that type and shall be established, to the extent practicable, consistent with the cooperative system for producing comparable and uniform health information and statistics described in section 306(e)(1) of the Public Health Service Act.

(b) The Secretary shall—

(1) monitor the operation of the systems established under subsection (a);

(2) assist with and support demonstrations and evaluations of the effectiveness and cost of the operation of such systems and encourage State adoption of such systems; and

(3) periodically revise such systems to improve their effectiveness and diminish their cost.

(c) The Secretary shall provide information obtained through use of the uniform reporting system described in subsection (a) in a useful manner and format to appropriate agencies and organizations, including health systems agencies (designated under section 1515 of the

Public Health Service Act) and State health planning and development agencies (designated under section 1521 of such Act), as may be necessary to carry out such agencies' and organizations' functions.

DISCLOSURE OF OWNERSHIP AND RELATED INFORMATION

SEC. 1124. (a)(1) The Secretary shall by regulation or by contract provision provide that each disclosing entity (as defined in paragraph (2)) shall—

(A) as a condition of the disclosing entity's participation in, or certification or recertification under, any of the programs established by titles V, XVIII, and XIX, or

(B) as a condition for the approval or renewal of a contract or agreement between the disclosing entity and the Secretary or the appropriate State agency under any of the programs established under titles V, XVIII, and XIX,

supply the Secretary or the appropriate State agency with full and complete information as to the identity of each person with an ownership or control interest (as defined in paragraph (3)) in the entity.

(2) As used in this section, the term "disclosing entity" means an entity which is—

(A) a provider of services (as defined in section 1861(u), other than a fund), an independent clinical laboratory, or a renal disease facility;

(B) an entity (other than an individual practitioner or group of practitioners) that furnishes, or arranges for the furnishing of, items or services with respect to which payment may be claimed by the entity under any plan or program established pursuant to title V or under a State plan approved under title XIX; or

(C) a carrier or other agency or organization that is acting as a fiscal intermediary or agent with respect to one or more providers of services (for purposes of part A or part B of title XVIII, or both, or for purposes of a State plan approved under title XIX) pursuant to (i) an agreement under section 1816, (ii) a contract under section 1842, or (iii) an agreement with a single State agency administering or supervising the administration of a State plan approved under title XIX.

(3) As used in this section, the term "person with an ownership or control interest" means, with respect to an entity, a person who—

(A)(i) has directly or indirectly (as determined by the Secretary in regulations) an ownership interest of 5 per centum or more in the entity; or

(ii) is the owner (in whole or in part) of an interest of 5 per centum or more in any mortgage, deed of trust, note, or other obligation secured (in whole or in part) by the entity or any of the property or assets thereof; or

(B) is an officer or director of the entity, if the entity is organized as a corporation; or

(C) is a partner in the entity, if the entity is organized as a partnership.

(b) To the extent determined to be feasible under regulations of the Secretary, a disclosing entity shall also include in the information supplied under subsection (a)(1), with respect to each person with

an ownership or control interest in the entity, the name of any other disclosing entity with respect to which the person is a person with an ownership or control interest.

(c) A provider of services (as defined in section 1861(u), other than a fund) shall also include in the information supplied under subsection (a)(1) full and complete information as to the identity of each person with an ownership or control interest in any subcontractor (as defined by the Secretary in regulations) in which the provider directly or indirectly has a 5 per centum or more ownership interest.

DISCLOSURE OF INDIVIDUALLY IDENTIFIABLE MEDICAL RECORDS

~~SEC. 1125. (a)(1) Notwithstanding any other provision of this Act except paragraph (2) of this subsection, no officer, employee, or agent of the United States, or any office, agency, or department thereof, or any Professional Standards Review Organization or any person acting or purporting to act on behalf of such Organization, may inspect, acquire, or require the disclosure of, for any reason whatever, any individually identifiable medical record of a patient, unless the patient has authorized such inspection, acquisition, or disclosure in accordance with subsection (b).~~

~~(2) The prohibition of paragraph (1) shall not apply to the inspection, acquisition, or disclosure of an individually identifiable medical record relating to medical care which is or was paid for (in whole or in part) under title V, XVIII, or XIX of this Act, if such inspection acquisition, or disclosure (A) is by a Professional Standards Review Organization, or any person acting or purporting to act on behalf of such organization, for the purpose of performing utilization review under part B of this title with respect to such medical care, or (B) is for the purpose of auditing for, investigating, or prosecuting fraud and abuse in the provision of, or payment for, such medical care.~~

~~(b) A patient authorizes an inspection, acquisition, or disclosure of an individually identifiable medical record for purposes of subsection (a) only if, in a signed and dated statement, he—~~

~~(1) authorizes the inspection, acquisition, or disclosure for a specific period of time;~~

~~(2) identifies the medical records authorized to be inspected, acquired, or disclosed;~~

~~(3) specifies the purposes for which the record may be inspected, acquired, or disclosed; and~~

~~(4) specifies the agencies which may inspect or acquire the record or to which the record may be disclosed.~~

~~(c) Any person who violates subsection (a), upon conviction, shall be fined not more than $10,000 or imprisoned for not more than five years, or both.~~

~~(d) In addition to any other remedy contained in this Act or otherwise available, injunctive relief shall be available to any person aggrieved by a violation or threatened violation of this section.~~

~~(e) The provisions of subsection (a) supersede any other law or any regulation of the United States which grants, or appears to grant, power or authority to any person to violate subsection (a), except those statutes which are enacted after the date of enactment of this section and which specifically refer to this section.~~

~~(f) For the purposes of this section, the term "individually identifiable medical record" means data or information that relates to the medical, dental, or mental condition or treatment of an individual and that is in a form which either identifies the individual or permits identification of the individual through means (whether direct or indirect) available to the public.~~

ISSUANCE OF SUBPENAS BY COMPTROLLER GENERAL

SEC. ~~1126~~ **1125.** *(a) For the purpose of any audit, investigation, examination, analysis, review, evaluation, or other function authorized by law with respect to any program authorized under section 226, titles V, XVIII, or XIX, or part B of this title of this Act, the Comptroller General of the United States shall have power to sign and issue subpenas to any person requiring the production of any pertinent books, records, documents, or other information. Subpenas so issued by the Comptroller General shall be served by anyone authorized by him (1) by delivering a copy thereof to the person named therein, or (2) by registered mail or by certified mail addressed to such person at his last dwelling place or principal place of business. A verified return by the person so serving the subpena setting forth the manner of service, or, in the case of service by registered mail or by certified mail, the return post office receipt therefor signed by the person so served, shall be proof of service.*

(b) In case of contumacy by, or refusal to obey a subpena issued pursuant to subsection (a) of this section and duly served upon, any person, any district court of the United States for the judicial district in which such person charged with contumacy or refusal to obey is found or resides or transacts business, upon application by the Comptroller General, shall have jurisdiction to issue an order requiring such person to produce the books, records, documents, or other information sought by the subpena; and any failure to obey such order of the court may be punished by the court as a contempt thereof. In proceedings brought under this subsection, the Comptroller General may be represented by attorneys employed in the General Accounting Office or by counsel whom he may employ without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and the provisions of chapter 51 and subchapters III and VI of chapter 53 of such title relating to classification and General Schedule pay rates.

(c)(1) Except as provided in paragraph (2), any employee or officer of the General Accounting Office who discloses a personal medical record (defined in paragraph (3)) to any person, other than an employee or officer of such Office whose official duties require disclosure of such information, shall be fined not more than $1,000 or imprisoned for not more than six months, or both, and charged the costs of prosecution.

(2) An employee or officer of the General Accounting Office who discloses a personal medical record to a Federal or State agency recognized by the Secretary as having responsibility for identifying and investigating cases or patterns of fraud or abuse shall not be subject to the penalties of paragraph (1) if the Comptroller General

has determined before the disclosure of such record that the record reveals evidence of fraud or abuse.

(3) For the purposes of this section, the term "personal medical record" means data or information—

(A) relating to the medical or mental condition or treatment of any individual;

(B) acquired by any employee or officer of the General Accounting Office in the course of any audit, investigation, examination, analysis, review, evaluation, or other function authorized by law with respect to any program authorized under section 226, titles V, XVIII, or XIX, or part B of this title of this Act; and

(C) in a form which can be associated with, or otherwise identify, directly or indirectly, the individual described in subparagraph (A).

(d) No personal medical record in the possession of the General Accounting Office shall be subject to subpena or discovery proceedings in a civil action.

DISCLOSURE BY INSTITUTIONS, ORGANIZATIONS, AND AGENCIES OF OWNERS AND CERTAIN OTHER INDIVIDUALS WHO HAVE BEEN CONVICTED OF CERTAIN OFFENSES

SEC. ~~1127~~ **1126.** *(a) As a condition of participation in or certification or recertification under the programs established by titles XVIII, XIX, and XX, any hospital, nursing facility, or other institution, organization, or agency shall be required to disclose to the Secretary or to the appropriate State agency the name of any person who—*

(1) has a direct or indirect ownership or control interest of 5 percent or more in such institution, organization, or agency or is an officer, director, agent, or managing employee (as defined in subsection (b)) of such institution, organization, or agency, and

(2) has been convicted (on or after the date of the enactment of this section, or within such period prior to that date as the Secretary shall specify in regulations) of a criminal offense related to the involvement of such person in any of such programs.

The Secretary or the appropriate State agency shall promptly notify the Inspector General in the Department of Health, Education, and Welfare of the receipt from any institution, organization, or agency of any application or request for such participation, certification, or recertification which discloses the name of any such person, and shall notify the Inspector General of the action taken with respect to such application or request.

(b) For the purposes of this section, the term "managing employee" means, with respect to an institution, organization, or agency, an individual, including a general manager, business manager, administrator, and director, who exercises operational or managerial control over the institution, organization, or agency, or who directly or indirectly conducts the day-to-day operations of the institution, organization, or agency.

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PART B—PROFESSIONAL STANDARDS REVIEW

* * * * * * *

DESIGNATION OF PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS

SEC. 1152. (a) * * *

(b) For purposes of subsection (a), the term "qualified organization" means—

(1) when used in connection with any area—

(A) an organization (i) which is a nonprofit professional association (or a component organization thereof), (ii) which is composed of licensed doctors of medicine or osteopathy engaged in the practice of medicine or surgery in such area, (iii) the membership of which includes a substantial proportion of all such physicians in such area, (iv) which is organized in a manner which makes available professional competence to review health care services of the types and kinds with respect to which Professional Standards Review Organizations have review responsibilities under this part, (v) the membership of which is voluntary and open to all doctors of medicine or osteopathy licensed to engage in the practice of medicine or surgery in such area without requirement of membership in or payment of dues to any organized medical society or association, and (vi) which does not restrict the eligibility of any member for service as an officer of the Professional Standards Review Organization or eligibility for and assignment to duties of such Professional Standards Review Organization, or, subject to subsection (c)[(i)](*1*),

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(2) an organization which the Secretary, on the basis of his examination and evaluation of a formal plan *which shall be developed and* submitted [to him] by the association, agency, or organization *in accordance with subsection* (*h*) (as well as on the basis of other relevant data and information), finds to be willing to perform and capable of performing, in an effective, timely, and objective manner and at reasonable cost, the duties, functions, and activities of a Professional Standards Review Organization required by or pursuant to this part.

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[(e) In order to avoid duplication of functions and unnecessary review and control activities, the Secretary is authorized to waive any or all of the review, certification, or similar activities otherwise required under or pursuant to any provision of this Act (other than this part) where he finds, on the basis of substantial evidence of the effective performance of review and control activities by Professional Standards Review Organizations, that the review, certification, and similar activities otherwise so required are not needed for the provision of adequate review and control.]

(*e*) *Where the Secretary finds a Professional Standards Review Organization* (*whether designated on a conditional basis or otherwise*) *to be competent to perform review responsibilities, the review, certification, and similar activities otherwise required pursuant to provisions of this Act* (*other than this part*) *shall not be applicable*

with respect to those providers, suppliers, and practitioners being reviewed by such Professional Standards Review Organization, except to the extent specified by the Secretary. Nothing in the preceding sentence shall be construed as rendering inapplicable any provision of this Act wherein requirements with respect to conditions for eligibility to or payment of benefits (as distinct from reviews and certifications made with respect to determinations of the kind made pursuant to paragraphs (1) and (2) of section 1155(a)) must be satisfied.

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(h)(1) During the development and preparation by an organization of its formal plan under subsection (b)(2) or of any modification of such plan to include review of services in skilled nursing facilities (as defined in section 1861(j)) or intermediate care facilities (as defined in section 1905(c)) or review of ambulatory care services, the organization shall consult with the single State agency responsible for administering or supervising the administration of the State plan approved under title XIX for the State in which the organization is located.

(2) Such plan and any such modification shall be submitted to the Governor of such State, at the time of its submission to the Secretary, for his comments.

(3) The Secretary, before making the findings described in subsection (b)(2) or a finding regarding the organization's capability to perform review of such services (as the case may be), shall consider any such comments submitted to him by such Governor before the end of the thirty-day period beginning on the date of submission of the plan or of any such modification (as the case may be).

(4) If, after considering such comments, the Secretary intends to make findings which are adverse to such comments, the Secretary shall provide the Governor making such comments with the opportunity to submit additional evidence and comments on such intended findings during a period of not less than thirty days ending before the findings become effective.

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TRIAL PERIOD FOR PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS

SEC. 1154. (a) * * *

(b) During any such trial period (which may not exceed [24] *48* months *except as provided in subsection (c)*), the Secretary may require a Professional Standards Review Organization to perform, *in addition to review of health care services provided by or in institutions*, only such of the duties and functions required under this part of Professional Standards Review Organization as he determines such organization to be capable of performing. The number and type of such duties shall, during the trial period, be progressively increased as the organization becomes capable of added responsibility so that, by the end of such period, such organization shall be considered a qualified organization only if the Secretary finds that it is substantially carrying out in a satisfactory manner, the activities and functions required of Professional Standards Review Organizations under this part with respect to the review of health care services provided [or ordered by physicians and other practitioners and institutional and

other health care facilities, agencies, and organizations] *by or in institutions (including ancillary services) and, in addition, review of such other health care services as the Secretary may require.* Any of such duties and functions not performed by such organization during such period shall be performed in the manner and to the extent otherwise provided for under law.

(c) If the Secretary finds that an organization designated under subsection (a) has been unable to perform satisfactorily all of the duties and functions required under this part for reasons beyond the organization's control, he may extend such organization's trial period for an additional period not exceeding twenty-four months.

[(c)] *(d)* Any agreement under which any organization is conditionally designated as the Professional Standards Review Organization for any area may be terminated by such organization upon 90 days notice to the Secretary or by the Secretary upon 90 days notice to such organization.

(e) In determining whether an organization designated on a conditional basis as the Professional Standards Review Organization for any area is substantially carrying out its duties in a satisfactory manner and should be considered a qualified organization, the Secretary shall follow the procedures specified in section 1152(h) (concerning the Secretary's consideration of comments of the Governor of the State in which the organization is located).

DUTIES AND FUNCTIONS OF PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS

SEC. 1155. (a) (1) Notwithstanding any other provision of law, but consistent with the provisions of this part, it shall [(subject to the provisions of subsection (g))] be the duty and function of each Professional Standards Review Organization for any area to assume, at the earliest date practicable, responsibility for the review of the professional activities in such area of physicians and other health care practitioners and institutional and noninstitutional providers of health care services in the provision of health care services (*except as provided in paragraph (7)*) and items for which payment may be made (in whole or in part) under this Act for the purpose of determining whether—

(A) such services and items are or were medically necessary;

(B) the quality of such services meets professionally recognized standards of health care; and

(C) in case such services and items are proposed to be provided in a hospital or other health care facility on an inpatient basis, such services and items could, consistent with the provision of appropriate medical care, be effectively provided on an outpatient basis or more economically in an inpatient health care facility of a different type.

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(6) No physician shall be permitted to review—

(A) health care services provided to a patient if he was directly [or indirectly involved in] *responsible for* providing such services, or

(B) health care services provided in or by an institution, organization, or agency, if he or any member of his family has, directly or indirectly, [any] *a significant* financial interest in such institution, organization, or agency.

For purposes of this paragraph, a physician's family includes only his spouse (other than a spouse who is legally separated from him under a decree of divorce or separate maintenance), children (including legally adopted children), grandchildren, parents, and grandparents.

(7) *A Professional Standards Review Organization located in a State has the function and duty to assume responsibility for the review under paragraph (1) of professional activities in intermediate care facilities (as defined in section 1905(c)) and in public institutions for the mentally retarded (described in section 1905(d)(1)) only if the Secretary finds, on the basis of such documentation as he may require from the State, that the single State agency which administers or supervises the administration of the State plan approved under title XIX for that State is not performing effective review of the quality and necessity of health care services provided in such facilities and institutions.*

* * * * * * *

(e)(1) Each Professional Standards Review Organization shall utilize the services of, and accept the findings of, the review committees of a hospital or other operating health care facility or organization (*other than a skilled nursing facility, as defined in section 1861(j)*) located in the area served by such organization, but only when and only to the extent and only for such time that such committees in such hospital or other operating health care facility or organization have demonstrated to the satisfaction of such organization their capacity effectively and in timely fashion to review activities in such hospital or other operating health care facility or organization (including the medical necessity of admissions, types and extent of services ordered, and lengths of stay) so as to aid in accomplishing the purposes and responsibilities described in subsection (a)(1), except where the Secretary disapproves, for good cause, such acceptance.

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(f)(1) * * *

(2) Any such agreement with an organization under this part shall provide that the Secretary make payments to such organization, *in a manner similar to that provided for under section 1816(c)*, equal to the amount of expenses reasonably and nesssarily incurred, as determined by the Secretary, by such organization in carrying out or preparing to carry out the duties and functions required by such agreement.

[(g) Notwithstanding any other provision of this part, the responsibility for review of health care services of any Professional Standards Review Organization shall be the review of health care services provided by or in institutions, unless such Organization shall have made a request to the Secretary that it be charged with the duty and function of reviewing other health care services and the Secretary shall have approved such request.]

(g)(1) Not later than two years after the date of the enactment of the Medicare-Medicaid Anti-Fraud and Abuse Amendments, the Secretary, through the conduct of demonstration projects or otherwise, shall develop effective ambulatory care review methodologies for use by Professional Standards Review Organizations in performing review responsibility with respect to ambulatory care services.

(2) Where a Professional Standards Review Organization (whether designated on a conditional basis or otherwise) requests review responsibility with respect to services furnished in shared health facilities, the Secretary must give priority to such request, with the highest priority being assigned to requests from organizations located in areas with substantial numbers of shared health facilities.

(3) The Secretary shall require any Professional Standards Review Organization which is capable of exercising review responsibility with respect to ambulatory care services to perform review responsibility with respect to such services on and after a date not later than two years after the date the organization has been designated as a Professional Standards Review Organization (other than under section 1154).

SUBMISSION OF REPORTS BY PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS

SEC. 1157. If, in discharging its duties and functions under this part, any Professional Standards Review Organization determines that any health care practitioner or any hospital, or other health care facility, agency, or organization has violated any of the obligations imposed by section 1160, such organization shall report the matter to the Statewide Professional Standards Review Council for the State in which such organization is located together with the recommendations of such Organization as to the action which should be taken with respect to the matter. Any Statewide Professional Standards Review Council receiving any such report and recommendation shall review the same and promptly transmit such report and recommendation to the Secretary together with any additional comments or recommendations thereon as it deems appropriate. [The Secretary may utilize a Professional Standards Review Organization, in lieu of a program review team as specified in sections 1862 and 1866, for purposes of subparagraph (C) of section 1862(d)(1) and subparagraph (F) of section 1866(b)(2).]

REQUIREMENT OF REVIEW APPROVAL AS CONDITION OF PAYMENT OF CLAIMS

SEC. 1158. (a) * * *

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(c) Where a Professional Standards Review Organization (whether designated on a conditional basis or otherwise) has been found competent by the Secretary to assume review responsiblitiy with respect to specific types of health care services or specified providers or practitioners of such services and is performing such reviews, determinations made pursuant to paragraphs (1) and (2) of section 1155 (a) in connection with such reviews shall constitute the conclusive

determination on those issues (subject to sections 1159, 1171(a)(1), and 1171(d)(3)) for purposes of payment under this Act, and no reviews with respect to those determinations shall be conducted, for purposes of payment, by agencies and organizations which are parties to agreements entered into by the Secretary pursuant to section 1816, carriers which are parties to contracts entered into by the Secretary pursuant to section 1842, or single State agencies administering or supervising the administration of State plans approved under title XIX.

OBLIGATIONS OF HEALTH CARE PRACTITIONERS AND PROVIDERS OF HEALTH CARE SERVICES; SANCTIONS AND PENALTIES; HEARINGS AND REVIEW

SEC. 1160. (a)(1) * * *

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(b)(1) If after reasonable notice and opportunity for discussion with the [practitioner or provider] *health care practitioner or hospital, or other health care facility, agency, or organization* concerned, any Professional Standards Review Organization submits a report and recommendations to the Secretary pursuant to section 1157 (which report and recommendations shall be submitted through the Statewide Professional Standards Review Council, if such Council has been established, which shall promptly transmit such report and recommendations together with any additional comments and recommendations thereon as it deems appropriate) and if the Secretary determines that such [practitioner or provider] *health care practitioner or hospital, or other health care facility, agency, or organization,* in providing health care services over which such organization has review responsibility and for which payment (in whole or in part) may be made under this Act has—

(A) by failing, in a substantial number of cases, substantially to comply with any obligation imposed on him under subsection (a), or

(B) by grossly and flagrantly violating any such obligation in one or more instances,

demonstrated an unwillingness or a lack of ability substantially to comply with such obligations, he (in addition to any other sanction provided under law) may exclude (permanently *or* for such period as the Secretary may prescribe) such [practitioner or provider] *health care practitioner or hospital, or other health care facility, agency, or organization* from eligibility to provide such services on a reimbursable basis.

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NATIONAL PROFESSIONAL STANDARDS REVIEW COUNCIL

SEC. 1163. (a)(1) There shall be established a National Professional Standards Review Council (hereinafter in this section referred to as the "Council") which shall consist of eleven physicians, not otherwise in the employ of the United States, appointed by the Secretary without regard to the provisions of title 5, United States Code, governing appointments in the competitive service.

(2) Members of the Council shall be appointed for a term of three years [and shall be eligible for reappointment], *except that of the members appointed in 1979, four shall be appointed for a term of only two years, and three for a term of only one year. Members of the Council shall be eligible for reappointment.*

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[(f) The National Professional Standards Review Council shall from time to time, but not less often than annually, submit to the Secretary and to the Congress a report on its activities and shall include in such report the findings of its studies and investigations together with any recommendations it may have with respect to the more effective accomplishment of the purposes and objectives of this part. Such report shall also contain comparative data indicating the results of review activities, conducted pursuant to this part, in each State and in each of the various areas thereof.]

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PROHIBITION AGAINST DISCLOSURE OF INFORMATION

SEC. 1166. (a) Any data or information acquired by any Professional Standards Review Organization, in the exercise of its duties and functions, shall be held in confidence and shall not be disclosed to any person except (1) to the extent that may be necessary to carry out the purposes of this part [or (2)], *(2)* in such cases and under such circumstances as the Secretary shall by regulations provide to assure adequate protection of the rights and interests of patients, health care practitioners, or providers of health care, *or (3) in accordance with subsection (b).*

(b) A Professional Standards Review Organization shall provide, in accordance with procedures established by the Secretary, data and information—

(1) to assist Federal and State agencies recognized by the Secretary as having responsibility for identifying and investigating cases or patterns of fraud or abuse, which data and information shall be provided by such Organization to such agencies at the request of such agencies at the discretion of such Organization on the basis of its findings with respect to evidence of fraud or abuse;

(2) to assist the Secretary, and such Federal and State agencies recognized by the Secretary as having health planning or related responsibilities under Federal or State law (including health systems agencies and State health planning and development agencies), in carrying out appropriate health care planning and related activities, which data and information shall be provided in such format and manner as may be prescribed by the Secretary or agreed upon by the responsible Federal and State agencies and such Organization, and shall be in the form of aggregate statistical data (without identifying any individual) on a geographic, institutional, or other basis reflecting the volume and frequency of services furnished, as well as the demographic characteristics of the population subject to review by such Organization.

The penalty provided in subsection (c) shall not apply to the disclosure of any data and information received under this subsection, except that such penalty shall apply to the disclosure (by the agency receiving such data and information) of any such data and information described in paragraph (1) unless such disclosure is made in a judicial, administrative, or other formal legal proceeding resulting from an investigation conducted by the agency receiving the data and information.

[(b)] (c) It shall be unlawful for any person to disclose any such information other than for such purposes, and any person violating the provisions of this section shall, upon conviction, be fined not more than $1,000, and imprisoned for not more than six months, or both, together with the costs of prosecution.

(d) No patient record in the possession of a Professional Standards Review Organization, a Statewide Professional Standards Review Council, or the National Professional Standards Review Council shall be subject to subpena or discovery proceedings in a civil action.

(e)(1) No officer, employee, or agent of a Professional Standards Review Organization may disclose to any officer, employee, or agent of the Federal Government and no officer, employee, or agent of the Federal Government may inspect (or have access to), any part of an individually identifiable medical record (as defined in paragraph (3)) of a patient which—

(A) is in the possession of a Professional Standards Review Organization, and

(B) relates to medical care which is not provided directly by the Federal Government or is not paid for (in whole or in part) under a Federal program or under a program receiving Federal financial assistance,

unless the patient has authorized such disclosure and inspection in accordance with paragraph (2).

(2) A patient authorizes disclosure and inspection of a medical record for purposes of paragraph (1) only if, in a signed and dated statement, he—

(A) authorizes the disclosure and inspection for a specific period of time;

(B) identifies the medical record authorized to be disclosed and inspected;

(C) specifies the purposes for which the record may be disclosed and inspected; and

(D) specifies the agencies which may inspect the record and to which the record may be disclosed.

(3) For purposes of this subsection:

(A) The term "individually identifiable medical record" means a medical, psychiatric, or dental record concerning an individual that is in a form which either identifies the individual or permits identification of the individual through means (whether direct or indirect) available to the public.

(B) The term "medical care" includes medical, psychiatric, and dental care and treatment.

LIMITATION ON LIABILITY FOR PERSONS PROVIDING INFORMATION, AND FOR MEMBERS AND EMPLOYEES OF PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS *AND STATEWIDE PROFESSIONAL STANDARDS REVIEW COUNCILS,* AND FOR HEALTH CARE PRACTITIONERS AND PROVIDERS

SEC. 1167. (a) Notwithstanding any other provision of law, no person providing information to any Professional Standards Review Organization *or to any Statewide Professional Standards Review Council*, shall be held, by reason of having provided such information, to have violated any criminal law, or to be civilly liable under any law, of the United States or of any State (or political subdivision thereof) unless—

(1) such information is unrelated to the performance of the duties and functions of such Organization *or such Council*, or

(2) such information is false and the person providing such information knew, or had reason to believe, that such information was false.

(b) (1) No individual who, as a member or employee of any Professional Standards Review Organization *or of any Statewide Professional Standards Review Council* or who furnishes professional counsel or services to such organization *or council*, shall be held by reason of the performance by him of any duty, function, or activity authorized or required of Professional Standards Review Organizations *or of Statewide Professional Standards Review Councils* under this part, to have violated any criminal law, (or to be civilly liable under any law, of the United States or of any State (or political subdivision thereof) provided he has exercised due care.

(2) The provisions of paragraph (1) shall not apply with respect to any action taken by any individual if such individual, in taking such action, was motivated by malice toward any person affected by such action.

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(d) The Secretary shall make payment to a Professional Standards Review Organization, whether conditionally designated or qualified, or to any member or employee thereof, or to any person who furnishes legal counsel or services to such organization, in an amount equal to the reasonable amount of the expenses incurred, as determined by the Secretary, in connection with the defense of any suit, action, or proceeding brought against such organization, member, or employee related to the performance of any duty or function of such organization, member, or employee (as described in section 1155).

AUTHORIZATION FOR USE OF CERTAIN FUNDS TO ADMINISTER THE PROVISIONS OF THIS PART

SEC. 1168. Expenses incurred in the administration of this part shall be payable from—

(a) funds in the Federal Hospital Insurance Trust Fund;

(b) funds in the Federal Supplementary Medical Insurance Trust Fund; and

(c) funds appropriated to carry out the health care provisions of the several titles of this Act:

in such amounts from each of the sources of funds (referred to in subsections (a), (b), and (c)) as the Secretary shall deem to be fair and

equitable after taking into consideration the costs attributable to the administration of this part with respect to each of such plans and programs. The Secretary shall make such transfers of moneys between the funds, referred to in clauses (a), (b) and (c) of the preceding sentence, as may be appropriate to settle accounts between them in cases where expenses properly payable from the funds described in one such clause have been paid from funds described in another of such clauses. *The Secretary shall make payments to Professional Standards Review Organizations (whether designated on a conditional basis or otherwise) from funds described in the first sentence of this section (without any requirement for the contribution of funds by any State or political subdivision thereof) for expenses incurred in the performance of duties by such Organizations.*

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MEMORANDUMS OF UNDERSTANDING; FEDERAL-STATE RELATIONS GENERALLY

SEC. 1171. (a) (1) Except as provided in paragraph (2), no determination made by a Professional Standards Review Organization pursuant to paragraphs (1) and (2) of section 1155(a) in connection with reviews shall constitute conclusive determinations under section 1158 (c) for purposes of payment under title XIX, unless such organization has entered into a memorandum of understanding, approved by the Secretary, with the single State agency responsible for administering or supervising the administration of the State plan approved under title XIX for the State in which the organization is located (hereinafter in this section referred to as the "State agency") for the purpose of delineating the relationship between the organization and the State agency and of providing for the exchange of data or information, administrative procedures, coordination mechanisms, and modification of the memorandum at any time that additional responsibility for review by the organization is authorized by the Secretary.

(2) The requirement of paragraph (1) may be waived by the Secretary if (A) the State agency indicates to the Secretary that it does not wish to enter into a memorandum of understanding with the organization involved, or (B) the Secretary finds that the State agency has refused to negotiate in good faith or in a timely manner with the organization involved.

(b) (1) The State agency may request a Professional Standards Review Organization which is entering into such a memorandum of understanding with the agency to include in the memorandum a specification of review goals or methods (additional to any such goals or methods contained in the organization's formal plan) for the performance of the organization's duties and functions under this part.

(2) If the agency and the organization cannot reach agreement regarding the inclusion of any such requested specification, the Secretary shall review such specification and shall require that the specification be included in the memorandum if the Secretary determines that such specification of goals or methods (A) is consistent with the functions of the organization under this part and with the provisions of title XIX and the State's plan approved under such title, and (B) does not seriously impact on the effectiveness and uniformity of the organization's review of health care services paid for under title XVIII and title XIX of this Act.

(c) *Notwithstanding any other provision of this Act, the State agency may contract with any Professional Standards Review Organization located in the State for the performance of review responsibilities in addition to those performed pursuant to this part (and the cost of performance of such additional responsibilities is reimbursable as an expense of the State agency under section 1903(a)) if—*

(1) the State agency formally requests the performance of such additional responsibilities, and

(2) the performance of such additional responsibilities is not inconsistent with this part and is provided for in an amendment to the State's plan which is approved by the Secretary under title XIX.

(d)(1) Each State agency may monitor the performance of review responsibilities by Professional Standards Review Organizations located within the State, in accordance with a State monitoring plan which is developed after review and comment by such organizations and is approved by the Secretary. The costs of activities of the State agency under and in accordance with such plan are reimbursable as an expense of the State agency under section 1903(a).

(2) A monitoring plan developed and approved under paragraph (1) may include a specification of performance criteria for judging the effectiveness of the review performance of the Professional Standards Review Organizations. If the State agency and the Professional Standards Review Organizations cannot reach agreement regarding such criteria, the Secretary shall assist the agency and organizations in resolving the matters in dispute.

(3)(A) Whenever a State agency monitoring the performance of review responsibilities by a Professional Standards Review Organization under a plan developed and approved under paragraph (1) submits to the Secretary reasonable documentation that the review determinations of such organization have caused an unreasonable and detrimental impact either on total State expenditures under title XIX or on the quality of care received by individuals under the State's plan approved under such title, and requests the Secretary to act, the Secretary shall, within thirty days from the date of receipt of the documentation, temporarily suspend such organization's authority in whole or in part under section 1158(c) to make conclusive determinations for purposes of payment under title XIX (and he may suspend such authority for purposes of payment under title XVIII) pending a reevaluation of such organization's performance of the responsibilities involved and any appropriate action the Secretary may take as a result of such reevaluation.

(B) The Secretary shall notify the State agency submitting such documentation, and the organization involved, in writing, of his determination, any subsequent actions taken, and the basis thereof, and shall notify the appropriate committees of the United States House of Representatives and the Senate of any such documentation submitted and the actions taken.

(e)(1) The Secretary shall in a timely manner establish procedures and mechanisms to govern his relationships with State agencies under this part (specifically including his relationships with such agencies in connection with their respective functions under the preceding provisions of this section). Such mechanisms shall include periodic con-

sultation by the Secretary with State agency representatives and representatives of Professional Standards Review Organizations regarding relationships between such agencies and such organizations (including the appropriate exchange of data and information between such agencies and such organizations) and other problems of mutual concern, and such procedures shall permit the State agency to be represented on any project assessments conducted by the Secretary with respect to a Professional Standards Review Organization located within its State.

(2) Each Professional Standards Review Organization shall provide to the State agency for the State in which it is located, upon request, data or information which the Secretary requires such organizations to report to him routinely on a periodic basis, and such other data or information as the Secretary authorizes to be disclosed.

ANNUAL REPORTS

SEC. 1172. The Secretary shall submit to the Congress not later than April 1, 1978, and not later than April 1 of each year thereafter, a full and complete report on the administration, impact, and cost of the program under this part during the preceding fiscal year, including data and information on—

(1) the number, status (conditional or otherwise), and service areas of, and review methodologies employed by, all Professional Standards Review Organizations participating in the program;

(2) the number of health care institutions and practitioners whose services are subject to review by Professional Standards Review Organizations, and the number of beneficiaries and recipients who received services subject to such review during such year;

(3) services determined, in accordance with the provisions of this part, to have been (A) medically unnecessary, (B) furnished in an inappropriate setting, or (C) deficient in quality;

(4) the imposition of penalties and sanctions under this title for violations of law and for failure to comply with the obligations imposed by this part;

(5) the total costs incurred under titles V, XI, XVIII, and XIX of this Act in the implementation and operation of all procedures required by such titles for the review of services to determine their medical necessity, appropriateness of use, and quality;

(6) changes in utilization rates and patterns, and changes in medical procedures and practices, attributable to the activities of Professional Standards Review Organizations;

(7) the progress being made among Professional Standards Review Organizations in adopting and implementing the ambulatory care review methodologies developed under section 1155(g)(1);

(8) the results of program evaluation activities, including the operation of data collection systems and the status of Professional Standards Review Organization data policy and implementation;

(9) the extent to which Professional Standards Review Organizations are performing reviews of services for other governmental or private health insurance programs; and

(10) recommendations for legislative changes.

MEDICAL OFFICERS IN AMERICAN SAMOA, THE NORTHERN MARIANA ISLANDS, AND THE TRUST TERRITORY OF THE PACIFIC ISLANDS TO BE INCLUDED IN THE PROFESSIONAL STANDARDS REVIEW PROGRAM

SEC. 1173. For purposes of applying this part (except sections 1155(c) and 1163) to American Samoa, the Northern Mariana Islands, and the Trust Territory of the Pacific Islands, individuals licensed to practice medicine in those places shall be considered to be physicians and doctors of medicine.

TITLE XVIII—HEALTH INSURANCE FOR THE AGED AND DISABLED

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PART A—HOSPITAL INSURANCE BENEFITS FOR THE AGED AND DISABLED

DESCRIPTION OF PROGRAM

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PAYMENT TO PROVIDERS OF SERVICES

SEC. 1815. (a) * * *

* * * * * * *

(c) No payment which may be made to a provider of services under this title for any service furnished to an individual shall be made to any other person under an assignment or power of attorney; but nothing in this subsection shall be construed (1) to prevent the making of such a payment in accordance with an assignment from the provider if such assignment is made to a governmental agency or entity or is established by or pursuant to the order of a court of competent jurisdiction, or (2) to preclude an agent of the provider of services from receiving any such payment if (but only if) such agent does so pursuant to an agency agreement under which the compensation to be paid to the agent for his services for or in connection with the billing or collection of payments due such provider under this title is unrelated (directly or indirectly) to the amount of such payments or the billings therefor, and is not dependent upon the actual collection of any such payment.

USE OF PUBLIC AGENCIES OR PRIVATE ORGANIZATIONS TO FACILITATE PAYMENT TO PROVIDERS OF SERVICES

SEC. 1816. (a) If any group or association of providers of services wishes to have payments under this part to such providers made through a national, State, or other public or private agency or organization and nominates such agency or organization for this purpose, the Secretary is authorized to enter into an agreement with such agency or organization providing for the determination by such agency or organization (subject to the provisions of section 1878 and to such review by the Secretary as may be provided for by the agreement) of the amount of the payments required pursuant to this part to be made to such providers (*and to providers assigned to such agency or organization under subsection (e)*), and for the making of

such payments by such agency or organization to such providers (*and to providers assigned to such agency or organization under subsection (e)*). Such agreement may also include provision for the agency or organization to do all or any part of the following: (1) to provide consultative services to institutions or agencies to enable them to establish and maintain fiscal records necessary for purposes of this part and otherwise to qualify as hospitals, extended care facilities, or home health agencies, and (2) with respect to the providers of services which are to receive payments through it (A) to serve as a center for, and communicate to providers, any information or instructions furnished to it by the Secretary, and serve as a channel of communication from providers to the Secretary; (B) to make such audits of the records of providers as may be necessary to insure that proper payments are made under this part; and (C) to perform such other functions as are necessary to carry out this subsection.

[(b) The Secretary shall not enter into an agreement with any agency or organization under this section unless (1) he finds (A) that to do so is consistent with the effective and efficient administration of this part, and (B) that such agency or organization is willing and able to assist the providers to which payments are made through it under this part in the application of safeguards against unnecessary utilization of services furnished by them to individuals entitled to hospital insurance benefits under section 226, and the agreement provides for such assistance, and (2) such agency or organization agrees to furnish to the Secretary such of the information acquired by it in carrying out its agreement under this section as the Secretary may find necessary in performing his functions under this part.]

(b) The Secretary shall not enter into or renew an agreement with any agency or organization under this section unless—

(1) he finds—

(A) after applying the standards, criteria, and procedures developed under subsection (f), that to do so is consistent with the effective and efficient administration of this part, and

(B) that such agency or organization is willing and able to assist the providers to which payments are made through it under this part in the application of safeguards against unnecessary utilization of services furnished by them to individuals entitled to hospital insurance benefits under section 226, and the agreement provides for such assistance; and

(2) such agency or organization agrees—

(A) to furnish to the Secretary such of the information acquired by it in carrying out its agreement under this section, and

(B) to provide the Secretary with access to all such data, information, and claims processing operations,

as the Secretary may find necessary in performing his functions under this part.

* * * * * * *

(e)(1) Notwithstanding subsections (a) and (d), the Secretary, after taking into consideration any preferences of providers of services, may assign or reassign any provider of services to any agency or organization which has entered into an agreement with him under this section, if he determines, after applying the standards, criteria, and

procedures developed under subsection (f), that such assignment or reassignment would result in the more effective and efficient administration of this part.

(2) Notwithstanding subsections (a) and (d), the Secretary may designate a national or regional agency or organization which has entered into an agreement with him under this section to perform functions under the agreement with respect to a class of providers of services in the Nation or region (as the case may be), if he determines, after applying the standards, criteria, and procedures developed under subsection (f), that such designation would result in more effective and efficient administration of this part.

(3)(A) Before the Secretary makes an assignment or reassignment under paragraph (1) of a provider of services to other than the agency or organization nominated by the provider, he shall furnish (i) the provider and such agency or organization with a full explanation of the reasons for his determination as to the efficiency and effectiveness of the agency or oragnization to perform the functions required under this part with respect to the provider, and (ii) such agency or organization with opportunity for a hearing, and such determination shall be subject to judicial review in accordance with chapter 7 of title 5, United States Code.

(B) Before the Secretary makes a designation under paragraph (2) with respect to a class of providers of services, he shall furnish (i) such providers and the agencies and organizations adversely affected by such designation with a full explanation of the reasons for his determination as to the efficiency and effectiveness of such agencies and organizations to perform the functions required under this part with respect to such providers, and (ii) the agencies and organizations adversely affected by such designation with opportunity for a hearing, and such determination shall be subject to judicial review in accordance with chapter 7 of title 5, United States Code.

(f) In order to determine whether the Secretary should enter into, renew, or terminate an agreement under this section with an agency or organization, whether the Secretary should assign or reassign a provider of service to an agency or organization, and whether the Secretary should designate an agency or organization to perform services with respect to a class of providers of services, the Secretary shall develop standards, criteria, and procedures to evaluate such agency's or organization's (1) overall performance of claims processing and other related functions required to be performed by such an agency or organization under an agreement entered into under this section, and (2) performance of such functions with respect to specific providers of services.

[e] *(g)* An agreement with the Secretary under this section may be terminated—

(1) by the agency or organization which entered into such agreement at such time and upon such notice to the Secretary, to the public, and to the providers as may be provided in regulations, or

(2) by the Secretary at such time and upon such notice to the agency or organization, to the providers which have nominated it for purposes of this section, and to the public, as may be provided in regulations, but only if he finds, *after applying the standards, criteria and procedures developed under subsection (f) and*

after reasonable notice and opportunity for hearing to the agency or organization, that (A) the agency or organization has failed substantially to carry out the agreement, or (B) the continuation of some or all of the functions provided for in the agreement with the agency or organization is disadvantageous or is inconsistent with the efficient administration of this part.

[f] (*h*) An agreement with an agency or organization under this section may require any of its officers or employees certifying payments or disbursing funds pursuant to the agreement, or otherwise participating in carrying out the agreement, to give surety bond to the United States in such amount as the Secretary may deem appropriate.

[g] (*i*) (1) No individual designated pursuant to an agreement under this section as a certifying officer shall, in the absence of gross negligence of intent to defraud the United States, be liable with respect to any payments certified by him under this section.

(2) No disbursing officer shall, in the absence of gross negligence or intent to defraud the United States, be liable with respect to any payment by him under this section if it was based upon a voucher signed by a certifying officer designated as provided in paragraph (1) of this subsection.

(3) No such agency or organization shall be liable to the United States for any payments referred to in paragraph (1) or (2).

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PART B—SUPPLEMENTARY MEDICAL INSURANCE BENEFITS FOR THE AGED AND DISABLED

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PAYMENT OF BENEFITS

SEC. 1833. (a) * * *

* * * * * * *

[(f) (1) In the case of the purchase of durable medical equipment included under section 1861 (s) (6), by or on behalf of an individual, payment shall be made in such amounts as the Secretary determines to be equivalent to payments that would have been made under this part had such equipment been rented and over such period of time as the Secretary finds such equipment would be used for such individual's medical treatment, except that (A) payment may be made in a lump sum if the Secretary finds that such method of payment is less costly or more practical than periodic payments, and (B) with respect to purchases of used equipment the Secretary is authorized to waive the 20 percent coinsurance amount applicable under subsection (a) whenever the purchase price of such equipment is at least 25 percent less than the reasonable charge for comparable new equipment.

[(2) In the case of rental of durable medical equipment the Secretary may, pursuant to agreements made with suppliers of such equipment, establish any reimbursement procedures (including payment on a lump sum basis in lieu of prolonged rental payments) which he finds to be equitable, economical, and feasible.]

(f) (1) In the case of durable medical equipment to be furnished an individual as described in section 1861 (s) (6), the Secretary shall determine, on the basis of such medical and other evidence as he finds

appropriate (including certification by the attending physician with respect to expected duration of need), whether the expected duration of the medical need for the equipment warrants a presumption that purchase of the equipment would be less costly or more practical than rental. If the Secretary determines that such a presumption does exist, he shall require that the equipment be purchased, on a lease-purchase basis or otherwise, and shall make payment in accordance with the lease-purchase agreement (or in a lump sum amount if the equipment is purchased other than on a lease-purchase basis); except that the Secretary may authorize the rental of the equipment notwithstanding such determination if he determines that the purchase of the equipment would be inconsistent with the purposes of this title or would create an undue financial hardship on the individual who will use it.

(2) With respect to purchases of used durable medical equipment, the Secretary may waive the 20 percent coinsurance amount applicable under subsection (a) whenever the purchase price of the used equipment is at least 25 percent less than the reasonable charge for comparable new equipment.

(3) For purposes of paragraph (1), the Secretary may, pursuant to agreements made with suppliers of durable medical equipment, establish reimbursement procedures which he finds to be equitable, economical, and feasible.

(4) The Secretary shall encourage suppliers of durable medical equipment to make their equipment available to individuals entitled to benefits under this title on a lease-purchase basis whenever possible.

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USE OF CARRIERS FOR ADMINISTRATION OF BENEFITS

SEC. 1842. (a) * * *
(b)(1) * * *

* * * * * * *

(5) No payment under this part for a service provided to any individual shall (except as provided in section 1870) be made to anyone other than such individual or (pursuant to an assignment described in subparagraph (B)(ii) of paragraph (3)) the physician or other person who provided the service, except that payment may be made (A) to the employer of such physician or other person if such physician or other person is required as a condition of his employment to turn over his fee for such service to his employer, or (B) (where the service was provided in a hospital, clinic, or other facility) to the facility in which the service was provided if there is a contractual arrangement between such physician or other person and such facility under which such facility submits the bill for such service. *No payment which under the preceding sentence may be made directly to the physician or other person providing the service involved (pursuant to an assignment described in subparagraph (B)(ii) of paragraph (3)) shall be made to anyone else under a reassignment or power of attorney (except to an employer or facility as described in clause (A) or (B) of such sentence); but nothing in this subsection shall be construed (i) to prevent the making of such a payment in accordance with an assignment from the individual to whom the service was provided or a reassignment*

from the physician or other person providing such service if such assignment or reassignment is made to a governmental agency or entity or is established by or pursuant to the order of a court of competent jurisdiction, or (ii) to preclude an agent of the physician or other person providing the service from receiving any such payment if (but only if) such agent does so pursuant to an agency agreement under which the compensation to be paid to the agent for his services for or in connection with the billing or collection of payments due such physician or other person under this title is unrelated (directly or indirectly) to the amount of such payments or the billings therefor, and is not dependent upon the actual collection of any such payment.

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Part C—Miscellaneous Provisions

Definition of Services, Institutions, Etc.

Sec. 1861. For purposes of this title.

Spell of Illness

(a) * * *

* * * * * * *

Skilled Nursing Facility

(j) The term "skilled nursing facility" means (except for purposes of subsection (a)(2)) an institution (or a distinct part of an institution) which has in effect a transfer agreement (meeting the requirements of subsection (1)) with one or more hospitals having agreements in effect under section 1866 and which—

(1) * * *

* * * * * * *

[(11) supplies full and complete information to the Secretary or his delegate as to the identity (A) of each person who has any direct or indirect ownership interest of 10 per centum or more in such skilled nursing facility or who is the owner (in whole or in part) of any mortgage, deed of trust, note, or other obligation secured (in whole or in part) by such skilled nursing facility or any of the property or assets of such skilled nursing facility, (B) in case a skilled nursing facility is organized as a corporation, of each officer and director of the corporation, and (C) in case a skilled nursing facility is organized as a partnership, of each partner; and promptly reports any changes which would affect the current accuracy of the information so required to be supplied;]

(11) complies with the requirements of section 1124;

* * * * * * *

Reasonable Cost

(v)(1)(A) * * *

* * * * * * *

(F) Such regulations shall require each provider of services (other than a fund) to make reports to the Secretary of information described

in section 1121(a) in accordance with the uniform reporting system (established under such section) for that type of provider.

Arrangements for Certain Services

(w)(1) The term "arrangements" is limited to arrangements under which receipt of payment by the hospital, a skilled nursing facility, or home health agency (whether in its own right or as agent), with respect to services for which an individual is entitled to have payment made under this title, discharges the liability of such individual or any other person to pay for the services.

(2) Utilization review activities conducted, in accordance with the requirements of the program established under part B of title XI of the Social Security Act with respect to services furnished by a hospital to patients insured under part A of this title or entitled to have payment made for such services under *part B of this title or under* a State plan approved under title V or XIX, by a Professional Standards Review Organization designated for the area in which such hospital is located shall be deemed to have been conducted pursuant to arrangments between such hospital and such organization under which such hospital is obligated to pay to such organization, as a condition of receiving payment for hospital services so furnished under this part or under such a State plan, such amount as is reasonably incurred and requested (as determined under regulations of the Secretary) by such organization in conducting such review activities with respect to services furnished by such hospital to such patients.

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EXCLUSIONS FROM COVERAGE

SEC. 1862. (a) * * *

* * * * * * *

(d)(1) No payment may be made under this title with respect to any item or services furnished to an individual by a person where the Secretary determines under this subsection that such person—

(A) has knowingly and willfully made, or caused to be made, any false statement or representation of a material fact for use in an application for payment under this title or for use in determining the right to a payment under this title;

(B) has submitted or caused to be submitted (except in the case of a provider of services), bills or requests for payment under this title containing charges (or in applicable cases requests for payment of costs to such person) for services rendered which the Secretary finds[, with the concurrence of the appropriate program review team appointed pursuant to paragraph (4),] to be substantially in excess of such person's customary charges (or in applicable cases substantially in excess of such person's costs) for such services, unless the Secretary finds there is good cause for such bills or requests containing such charges (or in applicable cases, such costs); or

(C) has furnished services or supplies which are determined by the Secretary, [with the concurrence of the members of the

appropriate program review team appointed pursuant to paragraph (4) who are physicians or other professional personnel in the health care field, to be substantially in excess of the needs of individuals or to be harmful to individuals or to be of a grossly inferior quality] *on the basis of reports transmitted to him in accordance with section 1157 of this Act (or, in the absence of any such report, on the basis of such data as he acquires in the administration of the program under this title), to be substantially in excess of the needs of individuals or to be of a quality which fails to meet professionally recognized standards of health care.*

* * * * * * *

[(4) For the purposes of paragraph (1)(B) and (C) of this subsection, and clause (F) of section 1866(b)(2), the Secretary shall, after consultation with appropriate State and local professional societies, the appropriate carriers and intermediaries utilized in the administration of this title, and consumer representatives familiar with the health needs of residents of the State, appoint one or more program review teams (composed of physicians, other professional personnel in the health care field, and the consumer representatives) in each State which shall, among other things—

[(A) undertake to review such statistical data on program utilization as may be submitted by the Secretary,

[(B) submit to the Secretary periodically, as may be prescribed in regulations, a report on the results of such review, together with recommendations with respect thereto,

[(C) undertake to review particular cases where there is a likelihood that the person or persons furnishing services and supplies to individuals may come within the provisions of paragraph (1)(B) and (C) of this subsection or clause (F) of section 1866(b)(2), and

[(D) submit to the Secretary periodically, as may be prescribed in regulations, a report of cases reviewed pursuant to subparagraph (C) along with an analysis of, and recommendations with respect to, such cases.]

(e)(1) Whenever the Secretary determines that a physician or other individual practitioner has been convicted (on or after the date of the enactment of this subsection, or within such period prior to that date as the Secretary shall specify in regulations) of a criminal offense related to such physician's or practitioner's involvement in the program under this title or the program under title XIX, the Secretary shall suspend such physician or practitioner from participation in the program under this title for such period as he may deem appropriate; and no payment may be made under this title with respect to any item or service furnished by such physician or practitioner during the period of such suspension. The provisions of paragraphs (2) and (3) of subsection (d) shall apply with respect to determinations made by the Secretary under this subsection.

(2) In any case where the Secretary under paragraph (1) suspends any physician or other individual practitioner from participation in the program under this title, he shall—

(A) promptly notify each single State agency which administers or supervises the administration of a State plan ap-

proved under title XIX of the fact, circumstances, and period of such suspension; and

(B) promptly notify the appropriate State or local agency or authority having responsibility for the licensing or certification of such physician or practitioner of the fact and circumstances of such suspension, request that appropriate investigations be made and sanctions invoked in accordance with applicable State law and policy, and request that such State or local agency or authority keep the Secretary and the Inspector General of the Department of Health, Education, and Welfare fully and currently informed with respect to any actions taken in response to such request.

* * * * * * *

AGREEMENTS WITH PROVIDERS OF SERVICES

SEC. 1866. (a)(1) Any provider of services (except a fund designated for purposes of section 1814(g) and section 1835(e)) shall be qualified to participate under this title and shall be eligible for payments under this title if it files with the Secretary an agreement—

(A) not to charge, except as provided in paragraph (2), any individual or any other person for items or services for which such individual is entitled to have payment made under this title (or for which he would be so entitled if such provider of services had complied with the procedural and other requirements under or pursuant to this title or for which such provider is paid pursuant to the provisions of section 1814(e)), and

(B) not to charge any individual or any other person for items or services for which such individual is not entitled to have payment made under this title because payment for expenses incurred for such items or services may not be made by reason of the provisions of paragraph (1) or (9), but only if (i) such individual was without fault in incurring such expenses and (ii) the Secretary's determination that such payment may not be made for such items and services was made after the third year following the year in which notice of such payment was sent to such individual; except that the Secretary may reduce such three-year period to not less than one year if he finds such reduction is consistent with the objectives of this title, and

(C) to make adequate provision for return (or other disposition, in accordance with regulations) of any moneys incorrectly collected from such individual or other person[.], *and*

(D) to promptly notify the Secretary of its employment of an individual who, at any time during the year preceding such employment, was employed in a managerial, accounting, auditing, or similar capacity (as determined by the Secretary by regulation) by an agency or organization which serves as a fiscal intermediary or carrier (for purposes of part A or part B, or both, of this title) with respect to the provider.

An agreement under this paragraph with a skilled nursing facility shall be for a term of not exceeding 12 months, except that the Secretary may extend such term for a period not exceeding 2 months, where

the health and safety of patients will not be jeopardized thereby, if he finds that such extension is necessary to prevent irreparable harm to such facility or hardship to the individuals being furnished items or services by such facility or if he finds it impracticable within such 12-month period to determine whether such facility is complying with the provisions of this title and regulations thereunder.

* * * * * * *

(3) The Secretary may refuse to enter into or renew an agreement under this section with a provider of services if any person who has a direct or indirect ownership or control interest of 5 percent or more in such provider, or who is an officer, director, agent, or managing employee (as defined in section ~~1127~~ 1126(b)) of such provider, is a person described in section ~~1127~~ 1126(a).

(b) An agreement with the Secretary under this section may be terminated (and in the case of a skilled nursing facility, prior to the end of the term specified in subsection (a)(1))—

(1) by the provider of services at such time and upon such notice to the Secretary and the public as may be provided in regulations, except that notice of more than 6 months shall not be required, or

(2) by the Secretary at such time and upon such reasonable notice to the provider of services and the public as may be specified in regulations, but only after the Secretary has determined (A) that such provider of services is not complying substantially with the provisions of such agreement, or with the provisions of this title and regulations thereunder, or (B) that such provider of services no longer substantially meets the applicable provisions of section 1861, or (C) that such provider of services has failed (*i*) to provide such information as the Secretary finds necessary to determine whether payments are or were due under this title and the amounts thereof, or has refused to permit such examination of its fiscal and other records by or on behalf of the Secretary as may be necessary to verify such information, *or* (*ii*) *to supply (within such period as may be specified by the Secretary in regulations) upon request specifically addressed to such provider by the Secretary (I) full and complete information as to the ownership of a subcontractor (as defined by the Secretary in regulations) with whom such provider has had, during the previous twelve months, business transactions in an aggregate amount in excess of $25,000, and (II) full and complete information as to any significant business transactions (as defined by the Secretary in regulations), occurring during the five-year period ending on the date of such request, between such provider and any wholly owned supplier or between such provider and any subcontractor,* or (D) that such provider has made, or caused to be made, any false statement or representation of a material fact for use in an application for payment under this title or for use in determining the right to a payment under this title, or (E) that such provider has submitted, or caused to be submitted, requests for payment under this title of amounts for rendering services substantially in excess of the costs incurred by such provider for rendering such services, or (F) that such provider has furnished services or sup-

plies which are determined by the Secretary [, with the concurrence of the members of the appropriate program review team appointed pursuant to section 1862(d)(4) who are physicians or other professional personnel in the health care field, to be substantially in excess of the needs of individuals or to be harmful to individuals or to be of a grossly inferior quality] *to be substantially in excess of the needs of individuals or to be of a quality which fails to meet professionally recognized standards of health care, or (G) that such provider (at the time the agreement was entered into) did not fully and accurately make any disclosure required of it by section 1127(a).*

* * * * * * *

PENALTIES

SEC. 1877. (a) Whoever—

(1) knowingly and willfully makes or causes to be made any false statement or representation of a material fact in any application for any benefit or payment under this title,

(2) at any time knowingly and willfully makes or causes to be made any false statement or representation of a material fact for use in determining rights to any such benefit or payment,

(3) having knowledge of the occurrence of any event affecting (A) his initial or continued right to any such benefit or payment, or (B) the initial or continued right to any such benefit or payment of any other individual in whose behalf he has applied for or is receiving such benefit or payment, conceals or fails to disclose such event with an intent fraudulently to secure such benefit or payment either in a greater amount or quantity than is due or when no such benefit or payment is authorized, or

(4) having made application to receive any such benefit or payment for the use and benefit of another and having received it, knowingly and willfully converts such benefit or payment or any part thereof to a use other than for the use and benefit of such other person,

[shall be guilty of a misdemeanor and upon conviction thereof shall be fined not more than $10,000 or imprisoned for not more than one year, or both.]

shall (i) in the case of such a statement, representation, concealment, failure, or conversion by any person in connection with the furnishing (by that person) of items or services for which payment is or may be made under this title, be guilty of a felony and upon conviction thereof fined not more than $25,000 or imprisoned for not more than five years or both, or (ii) in the case of such a statement, representation, concealment, failure, or conversion by any other person, be guilty of a misdemeanor and upon conviction thereof fined not more than $10,000 or imprisoned for not more than one year or both.

[(b) Whoever furnishes items or services to an individual for which payment is or may be made under this title and who solicits, offers, or receives any—

[(1) kickback or bribe in connection with the furnishing of such items or services or the making or receipt of such payment, or

[(2) rebate of any fee or charge for referring any such individual to another person for the furnishing of such items or services,

shall be guilty of a misdemeanor and upon conviction thereof shall be fined not more than $10,000 or imprisoned for not more than one year, or both.]

(b)(1) Whoever solicits or receives any remuneration (including kickbacks, bribes, or rebates, but excluding any amount paid by an employer to an employee for employment in the provision of covered items or services) directly or indirectly, overtly or covertly, in cash or in kind—

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of items or services for which payment may be made in whole or in part under this title, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing or ordering goods, facilities, services, or any item for which payment may be made in whole or in part under this title,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

(2) Whoever offers or pays any remuneration (including kickbacks, bribes, or rebates, but excluding any amount paid by an employer to an employee for employment in the provision of covered items or services) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—

(A) to refer an individual to a person for the furnishing or arranging for the furnishing of items or services for which payment may be made in whole or in part under this title, or

(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering goods, facilities, services, or any item for which payment may be made in whole or in part under this title,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

(3) Paragraphs (1) and (2) shall not apply to a discount or other reduction in price obtained by a provider of services or other entity reimbursed under this title on a cost basis if the reduction in price is properly disclosed and reflected in the costs claimed by the provider or entity as reimburable under this title.

(c) Whoever knowingly and willfully makes or causes to be made, or induces or seeks to induce the making of, any false statement or representation of a material fact with respect to the conditions or operation of any institution or facility in order that such institution or facility may qualify (either upon initial certification or upon recertification) as a hospital, skilled nursing facility, or home health agency (as those terms are defined in section 1861), shall be guilty of a [misdemeanor] *felony* and upon conviction thereof shall be fined not more than [$2,000] *$25,000* or imprisoned for not more than [6 months] *five years*, or both.

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TITLE XIX—GRANTS TO STATES FOR MEDICAL ASSISTANCE PROGRAMS

* * * * * * *

STATE PLANS FOR MEDICAL ASSISTANCE

SEC. 1902. (a) A State plan for medical assistance must—

(1) * * *

* * * * * * *

(27) provide for agreements with every person or institution providing services under the State plan under which such person or institution agrees (A) to keep such records as are necessary fully to disclose the extent of the services provided to individuals receiving assistance under the State plan, and (B) to furnish the State agency *or the Secretary* with such information, regarding any payments claimed by such person or institution for providing services under the State plan, as the State agency *or the Secretary* may from time to time request;

* * * * * * *

(32) provide that no payment under the plan for any care or service provided to an individual [by a physician, dentist, or other individual practitioner shall be made to anyone other than such individual or such physician, dentist, or practitioner, except that payment may be made (A) to the employer of such physician, dentist, or practitioner if such physician, dentist, or practitioner is required as a condition of his employment to turn over his fee for such care or service to his employer, or (B) (where the care or service was provided in a hospital, clinic, or other facility) to the facility in which the care or service was provided if there is a contractual arrangement between such physician, dentist, or practitioner and such facility under which such facility submits the bill for such care or service;] *shall be made to anyone other than such individual or the person or institution providing such care or service, under an assignment or power of attorney or otherwise; except that—*

(A) in the case of any care or service provided by a physician, dentist, or other individual practitioner, such payment may be made (i) to the employer of such physician, dentist, or other practitioner if such physician, dentist, or practitioner is required as a condition of his employment to turn over his fee for such care or service to his employer, or (ii) (where the care or service was provided in a hospital, clinic, or other facility) to the facility in which the care or service was provided if there is a contractual arrangement between such physician, dentist, or practitioner and such facility under which such facility submits the bill for such care or service; and

(B) nothing in this paragraph shall be construed (i) to prevent the making of such a payment in accordance with an assignment from the person or institution providing the care or service involved if such assignment is made to a governmental agency or entity or is established by or pursuant to the order of a court of competent jurisdiction, or (ii) to

preclude an agent of such person or institution from receiving any such payment if (but only if) such agent does so pursuant to an agency agreement under which the compensation to be paid to the agent for his services for or in connection with the billing or collection of payments due such person or institution under the plan is unrelated (directly or indirectly) to the amount of such payments or the billings therefor, and is not dependent upon the actual collection of any such payment;

* * * * * * *

[(35) effective January 1, 1973, provide that any intermediate care facility receiving payments under such plan must supply to the licensing agency of the State full and complete information as to the identity (A) of each person having (directly or indirectly) and ownership interest of 10 per centum or more in such intermediate care facility or who is the owner (in whole or in part) of any mortgage, deed of trust, note, or other obligation secured (in whole or in part) by such intermediate care facility or any of the property or assets of such intermediate care facility, (B) in case an intermediate care facility is organized as a corporation, of each officer and director of the corporation, and (C) in case an intermediate care facility is organized as a partnership, of each partner; and promptly report any changes which would affect the current accuracy of the information so required to be supplied; and]

(35) provide that any intermediate care facility receiving payments under such plan complies with the requirements of section 1124;

(36) provide that within 90 days following the completion of each survey of any health care facility, laboratory, agency, clinic, or organization, by the appropriate State agency described in paragraph (9), such agency shall (in accordance with regulations of the Secretary) make public in readily available form and place the pertinent findings of each such survey relating to the compliance of each such health care facility, laboratory, clinic, agency, or organization with (A) the statutory conditions of participation imposed under this title, and (B) the major additional conditions which the Secretary finds necessary in the interest of health and safety of individuals who are furnished care or services by any such facility, laboratory, clinic, agency, or organization[.] ;

(37) provide for claims payment procedures which (A) ensure that 90 per centum of claims for payment made for services covered under the plan and furnished by health care practitioners through individual or group practices or through shared health facilities are paid within 30 days of the date of receipt of such claims and that 99 per centum of such claims are paid within 60 days of the date of receipt of such claims, and (B) provide for procedures of prepayment and postpayment claims review, including review of appropriate data with respect to the recipient and provider of a service and the nature of the service for which payment is claimed, to ensure the proper and efficient payment of claims and management of the program;

(38) require that an entity (other than an individual practitioner or a group of practitioners) that furnishes, or arranges for the furnishing of, items or services under the plan, shall supply (within such period as may be specified in regulations by the Secretary or by the single State agency which administers or supervises the administration of the plan) upon request specifically addressed to such entity by the Secretary or such State agency, respectively, (A) full and complete information as to the ownership of a subcontractor (as defined by the Secretary in regulations) with whom such entity has had, during the previous twelve months, business transactions in an aggregate amount in excess of $25,000 and (B) full and complete information as to any significant business transactions (as defined by the Secretary in regulations), occurring during the five-year period ending on the date of such request, between such entity and any wholly owned supplier or between such entity and any subcontractor;

(39) provide that, subject to subsection (g), whenever the single State agency which administers or supervises the administration of a State plan approved under title XIX is notified by the Secretary under section 1862(e)(2)(A) that a physician or other individual practitioner has been suspended from participation in the program under title XVIII, the agency shall promptly suspend such physician or practitioner from participation in its plan under this title for not less than the period specified in such notice, and no payment may be made under its plan with respect to any items or service furnished by such physician or practitioner during the period of the suspension under this title; and

(40) require each health services facility or organization which receives payments under the plan and of a type for which a uniform reporting system has been established under section 1121(a) to make reports to the Secretary of information described in such section in accordance with the uniform reporting system (established under such section) for that type of facility or organization.

* * * * * * *

The requirement of clause (A) of paragraph (37) with respect to a State plan may be waived by the Secretary if he finds that the State has exercised good faith in trying to meet such requirement.

* * * * * * *

(g) The Secretary may waive suspension under subsection (a)(39) of a physician's or practitioner's participation in a State plan approved under this title and of the prohibition under such subsection of payment for items or services furnished by him during the period of such suspension, if the single State agency which administers or supervises the administration of a State plan approved under title XIX such plan submits a request to the Secretary for such waiver and if the Secretary approves such request.

PAYMENT TO STATES

SEC. 1903. (a) From the sums appropriated therefor, the Secretary (except as otherwise provided in this section) shall pay to each State

which has a plan approved under this title, for each quarter, beginning with the quarter commencing January 1, 1966

(1) * * *

* * * * * * *

(3) an amount equal to—

(A) (i) * * *

* * * * * * *

(B) 75 per centum of so much of the sums expended during such quarter as are attributable to the operation of systems (whether such systems are operated directly by the State or by another person under a contract with the State) of the type described in subparagraph (A) (i) (whether or not designed, developed, or installed with assistance under such subparagraph) which are approved by the Secretary and which include provision for prompt written notice to each individual who is furnished services covered by the plan, *or to each individual in a sample group of individuals who are furnished such services*, of the specific services (*other than confidential services*) so covered, the name of the person or persons furnishing the services, the date or dates on which the services were furnished, and the amount of the payment or payments made under the plan on account of the services; plus

(*6*) *subject to subsection* (*l*), *an amount equal to 90 per centum of so much of the sums expended during such quarter as are attributable to the arranging and providing of such programs of educational and technical assistance* (*provided through such means, including outreach offices, the media, and telephone hotlines, as the Secretary determines to be appropriate*) *to health care practitioners who furnish, through individual or group practices or through shared health facilities, services covered under the plan, as the Secretary determines are likely to expedite the filing and payment of claims for payment for such services provided by such practitioners; plus*

(*7*) *subject to subsection* (*b*) (*3*), *an amount equal to 90 per centum of the sums expended during each quarter beginning on or after October 1, 1977, and ending before October 1, 1980, with respect to costs incurred during such quarter* (*as found necessary by the Secretary for the elimination of fraud in the provision and administration of medical assistance provided under the State plan*) *which are attributable to establishment and operation of* (*including the training of personnel employed by*) *a State medicaid fraud control unit* (*described in subsection* (*p*)*; plus*

[(6)] (*8*) an amount equal to 50 per centum of the remainder of the amounts expended during such quarter as found necessary by the Secretary for the proper and efficient administration of the State plan.

(b) (1) Notwithstanding the preceding provisions of this section, the amount determined under subsection (a) (1) for any State for any quarter beginning after December 31, 1969, shall not take into account any amounts expended as medical assistance with respect to

individuals aged 65 or over and disabled individuals entitled to hospital insurance benefits under title XVIII which would not have been so expended if the individuals involved had been enrolled in the insurance program established by part B of title XVIII, other than amounts expended under provisions of the plan of such State required by section 1902(a)(34).

(2) For limitation on Federal participation for capital expenditures which are out of conformity with a comprehensive plan of a State or areawide planning agency, see section 1122.

(3) The amount of funds which the Secretary is otherwise obligated to pay a State during a quarter under subsection (a)(7) may not exceed the higher of—

(A) $125,000, or

(B) one-quarter of 1 per centum of the sums expended by the Federal, State, and local governments during the previous quarter in carrying out the State's plan under this title.

* * * * * * *

(i) Payment under the preceding provisions of this section shall not be made—

(1) with respect to any amount paid for items or services furnished under the plan after December 31, 1972, to the extent that such amount exceeds the charge which would be determined to be reasonable for such items or services under the fourth and fifth sentences of section 1842(b)(3); or

(2) with respect to any amount paid for services furnished under the plan after December 31, 1972, by a provider or other person during any period of time, if payment may not be made under title XVIII with respect to services furnished by such provider or person during such period of time solely by reason of a determination by the Secretary under section 1862(d)(1) or under clause (D), (E), or (F) of section 1866(b)(2), *or by reason of noncompliance with a request made by the Secretary under clause (C)(ii) of such section 1866(b)(2) or under section 1902(a)(38)*; or

* * * * * *

(g)(1) ~~With~~ **Subject to paragraph (3), with** respect to amounts paid for the following services furnished under the State plan after June 30, 1973 (other than services furnished pursuant to a contract with a health maintenance organization as defined in section 1876), the Federal medical assistance percentage shall be decreased as follows: After an individual has received care as an inpatient in a hospital (including an institution for tuberculosis), skilled nursing facility or intermediate care facility on 60 days, or in a hospital for mental diseases on 90 days (whether or not such days are consecutive), during any fiscal year, which for purposes of this section means the four calendar quarters ending with June 30, the Federal medical assistance percentage with respect to amounts paid for any such care furnished thereafter to such individual in the same fiscal year shall be decreased by 33⅓ per centum thereof unless the State agency responsible for the administration of the plan makes a showing satisfactory to the Secretary that, with respect to each calendar quarter for which the State submits a request for payment at the full Federal medical assistance

percentage for amounts paid for inpatient hospital services (including tuberculosis hospitals), skilled nursing facility services, or intermediate care facility services furnished beyond 60 days (or inpatient mental hospital services furnished beyond 90 days), there is in operation in the State an effective program of control over utilization of such services: such a showing must include evidence that—

(A) in each case for which payment is made under the State plan, a physician certifies at the time of admission, or, if later, the time the individual applies for medical assistance under the State plan (and recertifies, where such services are furnished over a period of time, in such cases, at least every 60 days, and accompanied by such supporting material, appropriate to the case involved, as may be provided in regulations of the Secretary), that such services are or were required to be given on an inpatient basis because the individual needs or needed such services; and

(B) in each such case, such services were furnished under a plan established and periodically reviewed and evaluated by a physician;

(C) such State has in effect a continuous program of review of utilization pursuant to section 1902(a)(30) whereby each admission is reviewed or screened in accordance with criteria established by medical and other professional personnel who are not themselves directly responsible for the care of the patient involved, and who do not have a significant financial interest in any such institution and are not, except in the case of a hospital, employed by the institution providing the care involved; and the information developed from such review or screening, along with the data obtained from prior reviews of the necessity for admission and continued stay of patients by such professional personnel, shall be used as the basis for establishing the size and composition of the sample of admissions to be subject to review and evaluation by such personnel, and any such sample may be of any size up to 100 per centum of all admissions and must be of sufficient size to serve the purpose of (i) identifying the patterns of care being provided and the changes occurring over time in such patterns so that the need for modification may be ascertained, and (ii) subjecting admissions to early or more extensive review where information indicates that such consideration is warranted; and

(D) such State has an effective program of medical review of the care of patients in mental hospitals, skilled nursing facilities, and intermediate care facilities pursuant to section 1902(a)(26) and (31) whereby the professional management of each case is reviewed and evaluated at least annually by independent professional review teams.

In determining the number of days on which an individual has received services described in this subsection, there shall not be counted any days with respect to which such individual is entitled to have payments made (in whole or in part) on his behalf under section 1812.

(2) The Secretary shall, as part of his validation procedures under this subsection, conduct **timely** sample onsite surveys of private and public institutions in which recipients of medical assistance may receive care and services under a State plan approved under this title,

and his findings with respect to such surveys (as well as the showings of the State agency required under this subsection) shall be made available for public inspection.

(3)(A) No decrease in the Federal medical assistance percentage of a State otherwise required to be imposed under paragraph (1) shall take effect—

(i) before January 1, 1978;

(ii) unless a notice of such decrease has been provided to the State at least 30 days before the date such decrease takes effect; and

(iii) due to the State's unsatisfactory or invalid showing made with respect to a calendar quarter beginning after September 30, 1977, unless notice of such decrease has been provided to the State no later than the first day of the fourth calendar quarter following the calendar quarter with respect to which such showing was made.

(B) The Secretary shall waive application of all or part (as is appropriate) of any decrease in the Federal medical assistance percentage of a State otherwise required to be imposed under paragraph (1) because a showing by the State, made under such paragraph with respect to a calendar quarter ending before October 1, 1977, is determined to be either unsatisfactory under such paragraph or invalid under paragraph (2), if the Secretary determines that the State's showing made under paragraph (1) with respect to the calendar quarter ending on December 31, 1977, is satisfactory under such paragraph and is valid under paragraph (2).

(4) No showing of a State with respect to a calendar quarter under paragraph (1) may be found satisfactory by the Secretary unless the showing—

(A) is submitted to the Secretary not later than the 30th day after the last day of the calendar quarter with respect to which it is submitted, unless the State demonstrates to the satisfaction of the Secretary good cause for not meeting such deadline; and

(B) demonstrates that the State has conducted an onsite inspection, as required by paragraphs (26) and (31) of section 1902(a), during the 12-month period ending on the last date of the calendar quarter—

(i) in each of not less than 98 per centum of the number of mental hospitals, skilled nursing facilities, and intermediate care facilities requiring such inspection, and

(ii) in every such hospital or facility which has 200 or more beds,

and that, with respect to such hospitals and facilities not inspected within such period, the State has exercised good faith and due diligence in attempting to conduct such inspections.

(4)(A) The Secretary may not find the showing of a State, with respect to a calendar quarter under paragraph (1), to be satisfactory if the showing is submitted to the Secretary later than the 30th day after the last day of the calendar quarter, unless the State demonstrates to the satisfaction of the Secretary good cause for not meeting such deadline.

(B) The Secretary shall find a showing of a State, with respect to a calendar quarter under paragraph (1), to be satisfactory under such paragraph with respect to the requirement that the State conduct annual on-site inspections in mental hospitals, skilled nursing facilities, and intermediate care facilities under paragraph (26) and (31) of section 1902(a), if the showing demonstrates that the State has conducted such an onsite inspection during the 12-month period ending on the last date of the calendar quarter—

(i) in each of not less than 98 per centum of the number of such hospitals and facilities requiring such inspection, and

(ii) in every such hospital or facility which has 200 or more beds,

and that, with respect to such hospitals and facilities not inspected within such period, the State has exercised good faith and due diligence in attempting to conduct such inspections.

(5) The Secretary shall submit to Congress, not later than 60 days after the end of each calendar quarter, a report on—

(A) his determination as to whether or not each showing, made under paragraph (1) by a State with respect to the calendar quarter, has been found to be satisfactory under such paragraph;

(B) his review (through onsite surveys and otherwise) under paragraph (2) of the validity of showings previously submitted by a State; and

(C) any reduction in the Federal medical assistance percentage he has imposed on a State because of its submittal under paragraph (1) of an unsatisfactory or invalid showing.

* * * * * * *

(3)(1) Payment shall not be made under subsection (a)(6) for a quarter ending after September 30, 1980.

(2) If the aggregate of the amounts of payments to be made in accordance with subsection (a) (6) for any calendar quarter to States exceeds $1,250,000, the amount of the payment to be made under such subsection for the quarter to each such State shall be an amount which bears the same ratio to the amount determined for the quarter under the subsection to the State as $1,250,000 bears to the amount required to make payments for the quarter in accordance with such subsection to all of the States.

* * * * * * *

(n) The State agency may refuse to enter into any contract or agreement with a hospital, nursing home, or other institution, organization, or agency for purposes of participation under the State plan, or otherwise to approve an institution, organization, or agency for such purposes, if any person who has a direct or indirect ownership or control interest of 5 percent or more in such institution, organization, or agency, or who is an officer, director, agent, or managing employee (as defined in section ~~1127~~ 1126(b)) of such institution, organization, or agency, is a person described in section ~~1127~~ 1126(a) (whether or not such institution, organization, or agency has in effect an agreement entered into with the Secretary pursuant to section 1866 or is subject to a suspension of payment order issued under subsection

(j) of this section); and, notwithstanding any other provision of this section, the State agency may terminate any such contract, agreement, or approval if it determines that the institution, organization, or agency did not fully and accurately make any disclosure required of it by section ~~1127~~ 1126(a) at the time such contract or agreement was entered into or such approval was given.

(o) Notwithstanding the preceding provisions of this section, no payment shall be made to a State under the preceding provisions of this section for expenditures for medical assistance provided for an individual under its State plan approved under this title to the extent that a private insurer (as defined by the Secretary by regulation) would have been obligated to provide such assistance but for a provision of its insurance contract which has the effect of limiting or excluding such obligation because the individual is eligible for or is provided medical assistance under the plan.

(p) For the purposes of this section, the term "State medicaid fraud control unit" means a single identifiable entity of the State government which the Secretary certifies (and annually recertifies) as meeting the following requirements:

(1) The entity **either (A)** *is a unit of the office of the State Attorney General or of another department of State government which possesses statewide authority to prosecute individuals for criminal violations,* **or (B) is in a State the constitution of which does not provide for the criminal prosecution of individuals by a statewide authority and has formal procedures, approved by the Secretary, which (i) assure its referral of suspected criminal violations relating to the program under this title to the appropriate authority or authorities in the State for prosecution and (ii) assure its assistance of, and coordination with, such authority or authorities in such prosecutions.**

(2) The entity is separate and distinct from the single State agency that administers or supervises the administration of the State plan under this title.

(3) The entity's function is conducting a statewide program for the investigation and prosecution of violations of all applicable State laws regarding any and all aspects of fraud in connection with any aspect of the provision of medical assistance and the activities of providers of such assistance under the State plan under this title.

(4) The entity has procedures for reviewing complaints of the abuse and neglect of patients of health care facilities which receive payments under the State plan under this title, and, where appropriate, for acting upon such complaints under the criminal laws of the State or for referring them to other State agencies for action.

(5) The entity provides for the collection, or referral for collection to a single State agency, of overpayments made under the State plan to health care facilities and discovered by the entity in carrying out its activities.

(6) The entity employs such auditors, attorneys, investigators, and other necessary personnel and is organized in such a manner

as is necessary to promote the effective and efficient conduct of the entity's activities.

(7) The entity submits to the Secretary an application and annual reports containing such information as the Secretary determines, by regulation, to be necessary to determine whether the entity meets the other requirements of this subsection.

* * * * * * *

PENALTIES

SEC. 1909. (a) Whoever—

(1) knowingly and willfully makes or causes to be made any false statement or representation of a material fact in any application for any benefit or payment under a State plan approved under this title,

(2) at any time knowingly and willfully makes or causes to be made any false statement or representation of a material fact for use in determining rights to such benefit or payment,

(3) having knowledge of the occurrence of any event affecting (A) his initial or continued right to any such benefit or payment, or (B) the initial or continued right to any such benefit or payment of any other individual in whose behalf he has applied for or is receiving such benefit or payment, conceals or fails to disclose such event with an intent fraudulently to secure such benefit or payment either in a greater amount or quantity than is due or when no such benefit or payment is authorized, or

(4) having made application to receive any such benefit or payment for the use and benefit of another and having received it, knowingly and willfully converts such benefit or payment or any part thereof to a use other than for the use and benefit of such other person,

[shall be guilty of a misdemeanor and upon conviction thereof shall be fined not more than $10,000 or imprisoned for not more than one year, or both.]

shall (i) in the case of such a statement, representation, concealment, failure, or conversion by any person in connection with the furnishing (by that person) of items or services for which payment is or may be made under this title, be guilty of a felony and upon conviction thereof fined not more than $25,000 or imprisoned for not more than five years or both, or (ii) in the case of such a statement, representation, concealment, failure, or conversion by any other person, be guilty of a misdemeanor and upon conviction thereof fined not more than $10,000 or imprisoned for not more than one year or both. In addition, in any case where an individual who is otherwise eligible for assistance under a State plan approved under this title is convicted of an offense under the preceding provisions of this subsection, the State may at its option (notwithstanding any other provision of this title or of such plan) limit, restrict, or suspend the eligibility of that individual for such period (not exceeding one year) as it deems appropriate; but the imposition of a limitation, restriction, or suspension with respect to the eligibility of any individual under this sentence shall not affect the eligibility of any other person for assistance under the plan, regardless of the relationship between that individual and such other person.

[(b) Whoever furnishes items or services to an individual for which payment is or may be made in whole or in part out of Federal funds under a State plan approved under this title and who solicits, offers, or receives any—

[(1) kickback or bribe in connection with the furnishing of such items or services or the making or receipt of such payment, or

[(2) rebate of any fee or charge for referring any such individual to another person for the furnishing of such items or services

shall be guilty of a misdemeanor and upon conviction thereof shall be fined not more than $10,000 or imprisoned for not more than one year, or both.]

(b) (1) Whoever solicits or receives any remuneration (including kickbacks, bribes, or rebates, but excluding any amount paid by an employer to an employee for employment in the provision of covered items or services) directly or indirectly, overtly or covertly, in cash or in kind—

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of items or services for which payment may be made in whole or in part under this title, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering goods, facilities, services, or any item for which payment may be made in whole or in part under this title,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than 5 years, or both.

(2) Whoever offers or pays any remuneration (including kickbacks, bribes, or rebates, but excluding any amount paid by an employer to an employee for employment in the provision of covered items or services) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—

(A) to refer an individual to a person for the furnishing or arranging for the furnishing of items or services for which payment may be made in whole or in part under this title, or

(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering goods, facilities, services, or any item for which payment may be made in whole or in part under this title,

shall be guilty of a felony and, upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than 5 years, or both.

(3) Paragraphs (1) and (2) shall not apply to a discount or other reduction in price obtained by an entity reimbursed under this title on a cost basis if the reduction in price is properly disclosed and reflected in the costs claimed by the entity as reimbursable under this title.

(c) Whoever knowingly and willfully makes or causes to be made, or induces or seeks to induce the making of, any false statement or representation of a material fact with respect to the conditions or operation of any institution or facility in order that such institution or facility may qualify (either upon initial certification or upon re-

certification) as a hospital, skilled nursing facility, intermediate care facility, or home health agency (as those terms are employed in this title) shall be guilty of a [misdemeanor] *felony* and upon conviction thereof shall be fined not more than [$2,000] *$25,000* or imprisoned for not more than [6 months] *five years*, or both.

* * * * * * *

TITLE XX—GRANTS TO STATES FOR SERVICES

* * * * * * *

PAYMENTS TO STATES

SEC. 2002. (a) (1) * * *

* * * * * * *

(15) Any State may refuse to enter into a contract or other arrangement with a provider of services for purposes of participation under the program established by this title, or otherwise to approve a provider for such purposes, if any person who has a direct or indirect ownership or control interest of 5 percent or more in such provider, or who is an officer, director, agent, or managing employee (as defined in section ~~1127~~ 1126(b) of such provider, is a person described in section ~~1127~~ 1126(a), and may terminate any such contract, arrangement, or approval if it determines that the provider did not fully and accurately make any disclosure required of it by section ~~1127~~ 1126(a) at the time the contract or arrangement was entered into or the approval was given.

* * * * * * *

SECTION 332 OF THE PUBLIC HEALTH SERVICE ACT

DESIGNATION OF HEALTH MANPOWER SHORTAGE AREAS

SEC. 332. (a) (1) * * *

* * * * * * *

(c) In determining whether to make a designation, the Secretary shall take into consideration the following:

(1) (A) The recommendations of each health systems agency (designated under section 1515) for a health service area which includes all or any part of the area, population group, medical facility, or other public facility under consideration for designation.

(B) The recommendations of the State health planning and development agency (designated under section 1521) if such area, population group, medical facility, or other public facility is within a health service area for which no health systems agency has been designated.

(2) The recommendations of the Governor of each State in which the area, population group, medical facility, or other pub-

lic facility under consideration for designation is in whole or part located.

(3) The extent to which individuals who are (A) residents of the area, members of the population group, or patients in the medical facility or other public facility under consideration for designation, and (B) entitled to have payment made for medical services under title XVIII or XIX of the Social Security Act, cannot obtain such services because of suspension of physicians from the programs under such titles.

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SECTION 204 OF THE ACT OF OCTOBER 15, 1976

(Public Law 94–505)

AN ACT To authorize conveyance of the interests of the United States in certain lands in Salt Lake County, Utah, to Shriners' Hospitals for Crippled Children, a Colorado corporation.

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TITLE II—OFFICE OF INSPECTOR GENERAL

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REPORTS

SEC. 204. (a) The Inspector General shall, not later than March 31 of each year, submit a report to the Secretary and to the Congress summarizing the activities of the Office during the preceding calendar year. Such report shall include, but need not be limited to—

(1) an identification and description of significant problems, abuses, and deficiencies relating to the administration of programs and operations of the Department disclosed by such activities;

(2) a description of recommendations for corrective action made by the Office with respect to significant problems, abuses, or deficiencies identified and described under paragraph (1);

(3) an evaluation of progress made in implementing recommendations described in the report or, where appropriate, in previous reports; and

(4) a summary of matters referred to prosecutive authorities and the extent to which prosecutions and convictions have resulted.

Such report shall also include an evaluation of the performance of the Attorney General in the investigation and prosecution of criminal violations relating to fraud in the programs of health insurance and medical assistance provided under titles XVIII and XIX of the Social Security Act, and shall include any recommendations with respect to improving the performance of such activities.

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SEPARATE VIEWS OF REPRESENTATIVE DAVID E. SATTERFIELD, III

The necessity for confidentiality in the relationship between doctor and patient has been appreciated for as long as medicine has been practiced. The duty of the physician to preserve the confidentiality of information obtained from his patients is explicitly recognized in the Hippocratic Oath and the American Medical Association's Principles of Ethics.

Fortunately, as a result of this recognition, the confidentiality of medical records has rarely been abused, and most patients assume that their privacy will be protected by the medical profession. Nevertheless, concern has been increasing that the ethics of the medical profession are no longer sufficient guaranty of the confidentiality of medical records. I see two basic reasons for this increased concern. First, the Health Care System of the United States is changing rapidly. The role of the Federal Government in paying for, providing and reviewing health care has increased enormously and all signs are that it will continue to increase. A growing percentage of health care is being provided by institutions—hospitals, HMO's, clinics—rather than by physicians practicing alone, and that care is more and more likely to be paid for by a third party. Consequently, when the individual patient provides sensitive information to a physician he may be placing that information within the control of an enormous, interlocking, health care bureaucracy. Secondly, the application of computer technology in the field of health care is steadily increasing. This development is described by Professor Alan F. Westin in a study prepared for the U.S. Department of Commerce [1]:

> Spokesmen from medicine and the computer industry expect the use of computers in doctor's offices and small clinics to move slowly but steadily upward in the next five years. They cite the increased exposure to computers that physicians receive as they treat their patients in hospitals; courses in medical schools about administrative and clinical uses of computers; the current trend toward greater group rather than solo practice, creating more practice units for which computers could be cost-effective; and the funding of various projects (such as CAPO) by federal health agencies to develop tested applications and encourage greater EDP use in doctors offices. Possibly the most important factor is the rapid price decline that is taking place in computing services, as small-system computers and minicomputers move into monthly costs for business data processing that many physicians are finding attractive." (at page 95)

[1] Westin, Alan F., Computers, Health Records, and Citizens Rights, Nat. Bur. Stand. (U.S., Monograph 157 (Dec. 1976)).

> As in doctor's offices, computer use in hospitals is changing the nature of the patient's file. In many hospitals in the pre-computer era, record-keeping was hit-or-miss, and though lots of paper accumulated in the record, these documents were often in disarray, without any indexing or current summary. Now, while the character of personal information that is being collected for automatic patient records is not different from what was recorded before, the automated personal data are being more systematically collected, more fully recorded and more centralized in permanent files. Patients processed through automatic history-taking are systematically asked to disclose the full range of physical, social, family, emotional and other personal data, and the resulting detailed patient profiles become a regular feature of the file, updated steadily as the patient remains with that care provider.
>
> From a health care standpoint, this is one of the most desirable features of automation—patient records are full, up-to-date, easily understood and are linked together from various departments and previous episodes. From a civil liberties standpoint, however, this trend means that all the medical and paramedical personnel in a facility who have access to the computerized files now have more detailed personal data and more comprehensive social histories than in the typical manual system, except for psychiatric facilities.
>
> In addition, computerization of patient data is facilitating (and is sometimes directly intended to facilitate) the sending of some automated patient data to organizations outside the primary care sector—to service payers and those charged with quality care assurance, and to the Zone 3 users such as public health agencies, welfare and rehabilitation programs, licensing authorities, judicial authorities, employment-insurance evaluators and so forth." (at pages 99–100)

In response to concern over these developments, the House Ways and Means Committee adopted an amendment to H.R. 3 which would limit the access of federal officers, employees, and agents to individually identifiable medical records without the consent of the patient. Unfortunately, this amendment would be overly broad and indiscriminate in its effects. It fails to make exceptions for those situations in which the health of the general public must override the right to privacy of the individual. For example, as Professor Westin points out:

> While securing informed, voluntary consent should cover most situations in which medical research and program evaluations need to be conducted, through the use of identified data from health systems, there will be situations in which this is not feasible.

I share the belief that statutory protection for the privacy of medical records is needed, especially with respect to access by federal employees to the records of individual patients whose medical care is not financed in whole or in part by the Federal Government. To legislate merely to limit the disclosure of medical information about a citizen obtained by federal employees without the knowledge or consent of

that patient is grossly inadequate. This belief has been strengthened by the recently released Department of HEW audit agency report, which revealed a shocking lack of security for computerized records of the Social Security Administration containing highly confidential personal information on millions of Americans. Particularly disturbing was the revelation that many federal employees have access to this personal information even though their jobs do not require such access.

I can think of no right more deserving of protection than the right to confidentiality of one's medical file. I do recognize, however, that there are occasions and circumstances when the public interest transcends the individual right, for example in cases of communicable disease. Even so, the accessability of a citizen's medical record in such circumstances should be clearly and carefully circumscribed. I can think of no better way to insure this protection of the public interest than to permit federal health officials to aid and assist the chief medical officer of the individual states when specifically requested to do so, and then only to the extent permitted by state law governing the authority of the chief medical authority in such state.

Accordingly, I shall offer an amendment which, except in the case of a medical emergency presenting an immediate threat to the life of an individual patient, would require federal officials, employees, or agents, before inspecting or requiring the disclosure of individually identifiable medical records, to obtain the written consent of the patient. It would further permit such inspection and disclosure when the federal health official or officials are requested to do so in writing, by an official authorized by state law to inspect or require the disclosure of medical records, with the further provision that the purpose and scope of authority to be exercised as well as the period of time such authority is delegated be also set forth in writing.

This basic safeguard would impose only a reasonable, minimal inconvenience on researchers and other federal health officials, an imposition which in my view is more than warranted by the added protection for individual privacy which it affords.

The amendment would not apply to alter the present rules governing access to medical records in the possession of the Armed Services or the Veterans' Administration. Nor would it apply to inspection of medical records in the course of (1) the delivery of medical care which is paid for or provided by the Federal Government, (2) review by PSROs of medical care paid for or provided by the Federal Government, and (3) auditing for, investigating, or prosecuting fraud and abuse in the provision of, or payment for, medical care which the Federal Government provides.

In drafting this amendment, I have taken great pains to insure that Federal assistance to State and local authorities in the control of communicable disease, the investigation of epidemics, and in epidemiologic research would not be unduly hampered.

It has been suggested that Congress should postpone action in this area until the final report of the Privacy Commission is received and the Department of HEW has had an opportunity to study the report and submit suggestions for legislation. This, of course, would virtually insure that no legislation governing the right of privacy in question will be enacted during this session of Congress. I do not feel such a delay is justified. A provision such as I propose is a careful

first step and is fully consistent with the Draft Medical Records Policy Recommendations of the Privacy Commission. Adoption of it would in no way preclude future legislation on this point. Again, Professor Westin's observations are pertinent:

> Predictably, there are divergent views among observers as to the nature and extensiveness of threats to privacy in various new helath care programs, in in the growth of automated data systems. But there is widespread agreement that dealing wisely and effectively with the privacy 'issue' is a vital matter, not only to the public's confidence in new health care institutions in the coming decade but also to the protection of fundamental citizen rights.
>
> The time is ripe, therefore, for focusing expert and public attention on these issues before changes in health care financing and review are enacted, before the new wave of computer applications and information systems unfold, and before arrangements to incorporate national patient identifiers and file-linking arrangements in the health field are put into place." (at page 2)

For the foregoing reasons, I urge my colleagues to support my amendment on the floor of the House when H.R. 3 is considered.

David E. Satterfield. III.

ADDITIONAL VIEWS BY MR. ROGERS

During the course of the Subcommittee consideration of H.R. 3, a significant amount of time and attention was devoted to the issue of the confidentiality of individually identifiable medical records. Much of the discussion centered around two alternative approaches:

(1) The approach adopted by the Ways and Means Committee, which bans all access to and inspection or disclosure of individually identifiable medical records by Federal employees, officers, agents, and PSRO's without specific, detailed, time-limited consent of the individual concerned, whether the care is paid for by public or private sources, with the following exceptions: (a) a PSRO may have access to the medical records of persons whose care was paid for by Medicare, Medicaid, or the maternal and child health program for the purpose of performing utilization review, or (b) the care is paid for by medicare, medicaid or the maternal and child health program, and inspection of the record is for purposes of auditing for, investigating or prosecuting fraud and abuse.

(2) The approach adopted by the Committee on Interstate and Foreign Commerce (a) which banned access or disclosure to Federal employees of individually identifiable medical records in the possession of the PSRO where the care was not paid for by Medicare, Medicaid or the maternal and child health program, without the specific consent of the patient, and (b) which required the Secretary of HEW to submit proposed legislation within three months of the issuance of the Privacy Protection Study Commission report, which embodies the recommendations of that group pertaining to the privacy of patients' medical records, the circumstances under which they may be examined, and the safeguards which should be established with respect to examination and disclosure.

The subcommitte received little evidence of abuse by Federal employees of their access to individually identifiable records. They did receive assurance that unwarranted disclosure is subject under current law to up to 1 year imprisonment and a fine of up to $1,000, or both, and loss of employment. While we felt a great deal of concern that the privacy of patient records should be protected, the subcommittee members also believed that certain vital activities to protect the health and safety of the population should not be unnecessarily impaired. Further, we were convinced by statements of members and staff of the Privacy Commission that translating the Commission's recommendations into law would require careful and time-consuming deliberations and painstaking attention to detail since the nuances of language are extremely important and can have far-reaching implications in this area. After weighing all aspects of the issue, the sub-

committee determined that it was the prudent and appropriate course to wait until the Privacy Commission's final report was issued, to allow the administration to formulate suggested legislation, to hold public hearings on the legislation and other legislative approaches that might be suggested by Members, and then report a bill to the House which we can recommend with assurance.

During the full committee consideration of H.R. 3, my colleague, the Honorable David Satterfield, proposed an amendment concerning confidentiality of medical records which, while patterned on the approach followed by the Ways and Means Committee, provided additional exceptions to the ban on Federal access to records without specific individual consent. These exceptions included (a) the inspection or disclosure is made on the specific request of an official authorized under State law to inspect or require the disclosure of records, and whose request states the specific purpose of the disclosure, who may inspect the record, over what time period, etc.; (b) the inspection or disclosure is made to meet a medical emergency presenting an immediate threat to human life; (c) the care is paid for in whole or part by the Federal government and access to the record is for the purpose of providing care, is by a PSRO or others to carry out utilization review, or is to investigate fraud or abuse, or (d) the access is authorized by legislation relating to the armed forces or veterans benefits. While the amendment proposed by Congressman Satterfield removes some of the objections to the more stringent amendment adopted by the Ways and Means Committee, it by no means addresses sufficiently the problems heard in testimony before the subcommittee.

First, although the proposed amendment sets up an exception for instances of medical emergency, access to medical records is often needed to determine whether or not there is in fact an emergency. The records themselves disclose the facts upon which action by the Center for Disease Control, for example, is predicated. Such access would be precluded by this amendment. Because of this, the restrictions contained in the amendment would undermine the investigations of epidemics, the search for causes and prevention of disease, and the monitoring of the quality of research on new drugs.

Investigation of an epidemic might appear to be manageable with the Satterfield provision for access upon the request of a State official. But this is not the case. The Center for Disease Control in fact does not now investigate epidemics or perform hospital or medical record review without the State's request or agreement. But if State legislative authority of the specificity required in this amendment becomes the basis for future cooperation, immediate and complicated legal problems will certainly surface. There are substantial variations in legislative authority, state by state, for such requests for assistance. HEW has estimated that in one quarter of the States, the authorities—particularly relating to chronic, occupational, and environmentally related disease—are vague or nonexistent. Doubts and confusion about the authority of State officials to authorize Federal access under this amendment would complicate the currently smooth, productive, effective Federal-state cooperation in disease control. Prompt investigation of epidemics would almost certainly be impeded.

Research into the origins and course of disease would be also halted. Access to records for long-range research purpose is not appropriate keyed to the authority of State officials, whose authority to inspect

or require disclosure of records is typically not explicit. Neither does "medical emergency" exception offer much basis for investigating the course of an illness like cancer in a large population over a period of time.

It is a cruel distinction to permit disclosure when the danger is immediate, but to deny to future generations the possibility of elucidating the origins of the disease and developing measures for prevention or cure.

In assuring the quality of research used in support of new drug applications, it is sometimes necessary to inspect the records of patients to whom the drugs were administered. This is essential to establishing that drugs are safe for public use. Requiring prior consent would prevent this, because it is impossible to know the identity of the patient before examining the record.

The work of the National Institute for Occupational Safety and Health (NIOSH) could also be adversely affected. The Institute's research has been vital to establishing standards protecting many thousands of American workers from such cancer-causing agents as asbestos, vinyl chloride, coke oven emissions, and 14 chemical carcinogens.

Many occupational diseases, particularly occupationally-induced cancer, take many years to develop. To establish cause and effect relationships between exposure and disease, NIOSH may need access to all plant medical records for certain employees going back as many as 20 or 30 years. Frequently those employees are no longer at the plant and may not be readily available to give permission for examination of their records.

There could also be a problem if the workers were still employed at the plant. If individual consent were required for examination of those records, an employer would be in a position to discourage his employees from permitting access to employment-related medical records, thus preventing a thorough assessment of the health risks at the plant.

An additional concern is that the proposed amendment sets up a double standard, one for Veterans, employees of the Defense Department and those whose care is financed by the United States, and another for the balance of the residents of this country. David F. Linowes, Chairman of the Privacy Commission, has stated that this differs from the Commission approach which seeks to establish uniform standards for all medical record information. Differentiation of the rights to privacy on the basis of who pays for the care is not a precedent which should be accepted lightly. If such a differentiation is to be made, surely it should be limited to inspection of records, not disclosure of them.

This is only an initial set of concerns with the aproach suggested by my colleague. I have no doubt that further study of the amendment and its review by persons engaged in public health, cancer research, and similar activities would uncover more problems. It seems apparent that legislation in this complex area should build on the Privacy Commission Study and should not be adopted in haste. It should be carefully reviewed in a full set of legislative hearings with the benefit of the advice and consultation of the public. That, in my view, is the only responsible course for the Congress to follow.

PAUL G. ROGERS.

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